US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Delayed Receipt of Patients' Colorectal Cancer Screening Tests at the Phoenix VA Health Care System in Arizona

Healthcare Inspection | **23-00383-21** | **November 14, 2023**

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations of delays in the receipt of patients' colorectal cancer (CRC) screening tests at the Phoenix VA Health Care System (facility) in Arizona. Specifically, on September 9, 2022, the OIG received a complaint alleging that more than 400 fecal immunochemical tests (FITs), a type of CRC screening test, were delivered to the facility in June 2022 after being held in a non-VA warehouse for more than 30 days because of unpaid postage bills.[1] The OIG opened the inspection to determine whether there was a

- delay in the receipt of more than 400 patient FITs,
- failure to protect the personal identifying information of affected patients, and
- delay in the affected patients receiving further evaluation and care, when warranted.

During the inspection, the OIG identified additional concerns related to proper handling and recording of FIT specimens, ensuring FIT specimen stability prior to processing, and missed opportunities to address specimen collection dates.[2]

Colorectal Cancer and Screening

CRC, a cancer located in the colon or rectum, is the third leading cause of cancer death for both men and women in the United States.[3] Most CRCs arise from precancerous growths (polyps) that form on the inner lining of the colon or rectum. Most polyps are non-cancerous (benign), but over time, some can develop into cancer (malignant). Early detection and removal of polyps can prevent cancer from forming and promote a full recovery from benign or precancerous polyps. As CRC "rarely causes symptoms in its early stages, screening for the disease is important."[4] In 2021, the US Preventive Services Task Force updated their recommendation to begin CRC screening in asymptomatic, average-risk adults at the age of 45 (previously age 50).[5]

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[1] The complainant reported 408 FITs. During the inspection, facility documentation indicated the number to be either 406 or 407. The OIG reviewed the data but could not clearly discern the number. The OIG refers to the number of FITs as 406 throughout this report based on initial documentation.

[2] *Merriam-Webster.com Dictionary*, "specimen," accessed February 14, 2023, https://www.merriam-webster.com/dictionary/specimen; *Merriam-Webster.com Dictionary*, "sample," accessed February 14, 2023, https://www.merriam-webster.com/dictionary/sample. In this report, the OIG uses the term "specimen" to indicate the stool sample collected in the FIT vial. The terms specimen and sample are often interchangeable.

[3] Siegel, RL, Miller, KD, Wagle, NS, Jemal, A. "Cancer statistics, 2023," *CA Cancer J Clin*. 2023; 73(1): 17-48. https://doi.org/10.3322/caac.21763.

[4] VA, Veterans Health Library, "Colorectal Cancer Screening," accessed February 14, 2023, https://www.veteranshealthlibrary.va.gov/RelatedItems/142,87081_VA.

[5] US Preventive Services Task Force, "Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement," *JAMA.* 2021;325(19):1965–1977, https://doi.org/10.1001/jama.2021.6238.

In alignment with the US Preventive Services Task Force recommendations, it is Veterans Health Administration (VHA) policy to recommend CRC screening to average-risk patients ages 45 through 75.[6] VHA's preferred method of CRC screening for patients at average risk for CRC is the FIT.[7] The FIT is a stool-based test that detects the presence of blood in the stool that may be indicative of colon polyps or cancer.[8] The FIT specimen is time sensitive. Once collected and placed in the vial, the stool specimen is stable for 15 days at room temperature or 30 days when refrigerated.[9] The specimen's stability is important, as a delay between the date and time the specimen is collected and when it is delivered and processed in the laboratory decreases the test performance and increases the likelihood of false-negative test results.[10]

At the facility, primary care providers place an order for a FIT and nurses or laboratory staff distribute the FIT kit to the patient. The patient collects the stool specimen at home using the enclosed manufacturer's instructions and mails the specimen to the facility's main laboratory in the business reply envelope provided. The United States Postal Service (USPS) delivers mail containing patient FIT specimens to the facility, where it is distributed to the laboratory for testing.

Inspection Results

The OIG substantiated that 406 patient FITs were held in a USPS station for approximately 60 days due to an unpaid postage bill by the facility. The delay resulted in laboratory staff's inability to process 403 (99 percent) of the patient FITs because the specimens were outside the

[6] VHA Directive 1015, *Colorectal Cancer Screening*, April 3, 2020, amended November 22, 2022. The directive was amended after the events discussed in this report; however, neither the language nor the content relevant to and included in this report was changed.

[7] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) (11), "Implementation of Programmatic Mailed Fecal Immunochemical Testing (FIT) for Colorectal Cancer Screening (VIEWS 9018428)," memorandum to VISN Directors, VISN Chief Medical Officers, VISN Integrated Clinical Community Leads for Specialty Care, Diagnostics and Primary Care, December 20, 2022.

[8] US Preventive Services Task Force; Veterans Health Library.

[9] Polymedco, *OC-Auto® Micro 80 iFOB Test*, June 2, 2016. MIC 1013 OC-80, *Auto Micro Fecal Immunochemical Test (FIT)*, July 6, 2018, reviewed and approved April 8, 2022. For the purposes of this report, a specimen is considered stable when its structure remains unchanged. Changes in conditions, such as temperature and time, may affect the stability of the specimen and the outcome of the lab result. Due to the nature of the test involving patients collecting specimens at home and mailing FITs to the facility, stability cannot be assured beyond room temperature conditions; therefore, the OIG considers specimens to be stable for 15 days.

[10] L.G.M. van Rossum, A.F. van Rijn, M.G.H. van Oijen, P. Fockens, R.J.F. Laheij, A.L.M. Verbeek, J.B.M.J. Jansen, and E. Dekker (2009), "False negative fecal occult blood tests due to delayed sample return in colorectal cancer screening," *International Journal of Cancer*, 125: 746-750, 2009, https://doi.org/10.1002/ijc.24458; National Cancer Institute, "false-negative test result," accessed June 4, 2023, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/false-negative-test-result. A false-negative test result "indicates that a person does not have a specific disease or condition when the person actually does have the disease or condition."

stability period.[11] The OIG found that a person-dependent payment process, change in supervisors, and failure to transfer key knowledge regarding USPS postage bills and payment processes resulted in the breakdown. Once apprised of the situation, the logistics supervisor at the facility implemented an automatic payment program to prevent future mail disruptions.

Per facility policy, laboratory staff are responsible for recording each specimen into the patient's electronic health record (EHR) by the order number, assigning an accession number, and ensuring the specimen meets requirements for testing; a specimen that cannot be processed must be canceled or deleted, with a comment explaining why the test is not being processed and tested.[12] The OIG determined that 403 FIT specimens, found to be outside of the 15-day stability period, were not accessioned according to laboratory policy, and non-laboratory staff made decisions regarding the specimens' stability.[13]

The OIG learned that because of the limited availability of laboratory staff, and in an effort to ensure the 406 FIT specimens were acted upon timely, facility Quality, Safety, and Improvement (QSI) staff reviewed and recorded available patient information from the FIT vials, including the specimen collection date; however, laboratory staff did not enter the information in the patients' EHRs. Instead, the patient aligned care team (PACT) coordinator followed up with the patients affected by the delayed FIT specimens as part of a rescreening plan. Although aware of the delay, neither the facility acting chief of pathology and laboratory medicine nor the Veterans Integrated Service Network (VISN) 22 Chief of Pathology and Laboratory Medicine Services were aware of the processes and decisions regarding the handling and disposition of the FIT specimens. Consequently, the acting chief of pathology and laboratory medicine could not ensure the FITs were accessioned properly.

The OIG did not substantiate that patients' personally identifiable information from FITs, including specimen vials, was not properly disposed of or protected. The OIG found staff properly disposed of items containing patients' personally identifiable information items in biohazard receptacles.

The OIG did not substantiate a delay in further evaluation and care for the patients whose FITs were outside of the stability period and could not be tested. The OIG found that facility staff acted quickly to identify the patients who were affected, developed a reasonable follow-up plan, and took appropriate measures to ensure affected patients were screened or further evaluated for

[11] The QSI program manager provided documentation to the OIG that 3 of the 406 FITs were processed. The OIG did not independently validate the provided information.

[12] SAQ 1010, "Accessioning and Processing of Laboratory Specimens," April 26, 2022. Facility policy describes accessioning as the process of receiving, inspecting, and recording or scanning specimens into a patient's electronic health record.

[13] SAQ 1010.

colorectal cancer. Further, the OIG's independent review of selected patients did not identify an adverse clinical outcome related to the delay in CRC screening.[14]

During the inspection, the OIG team learned that when QSI staff reviewed and collected patient information from the delayed FITs, patients did not record the collection date on 351 of the 406 specimens (86 percent). Due to the significant number of FITs that did not have the collection date, the OIG became concerned about the prevalence of this omission in all FIT specimens received and processed at the facility.

The OIG reviewed this concern and found the laboratory manager and staff lacked knowledge and clarity about FIT specimen stability and storage requirements, processed FIT specimens regardless of whether the date of collection was recorded or known, and at times, recorded the collection date as the date the specimen was received or processed.

The OIG found that PACT and laboratory staff's use of pre-printed, patient-specific FIT labels contributed to the omission of collection dates on the FIT vials and may have contributed to laboratory staff's practice of referencing the test order date when determining specimen stability. Through observation and interviews, the OIG noted that, although FIT vials with the original manufacturer's labels had a space for patients to complete the date of collection, the pre-printed labels without a space for the collection date were placed over the manufacturer's labels. The OIG concluded that a lack of PACT awareness of the importance of the collection date in determining the specimen's stability contributed to the ongoing use of the pre-printed labels and lack of, or inconsistent, guidance given to patients.

The OIG determined that facility and service line leaders missed opportunities to evaluate and resolve identified FIT labeling issues that were indicative of broader laboratory FIT processing failures. Facility leaders did not address omitted collection dates despite QSI staff finding that 86 percent of FITs did not have a collection date. Given the magnitude and clinical significance of this issue, the OIG would have expected leaders to evaluate the frequency and cause of the omission for all FITs and the impact on either specimen rejection rates or compromised test results due to processing specimens outside of the stability period.

Due to the significance of the FIT processing concern, the OIG spoke with VISN and facility leaders on April 27, 2023. The OIG informed leaders that laboratory staff were improperly processing FIT specimens, explained the circumstances that led to the finding, and discussed the potential impact on patients who may have received false-negative test results. The OIG recommended leaders begin reviewing FIT processing practices and taking actions to ensure FIT specimen stability standards were met. Leaders were unaware of the processing issues brought

[14] Within the context of this report, the OIG considered adverse clinical outcomes to be defined as death, hospitalization, or significant change in the status of a patient's health, that in the OIG's assessment, may have been preventable if a positive result from the CRC screening had been identified when the patient originally returned the FIT specimen in the spring of 2022.

forward, receptive to and concerned about the information received, and eager to discuss immediate actions.

The OIG made two recommendations to the VISN Director related to oversight of facility leaders' review of laboratory FIT processing practices, and evaluation of the patient impact of potential false-negative results.

The OIG made three recommendations to the Facility Director related to reviewing and ensuring compliance with processes completed for the delayed and future FIT specimens received by the laboratory; establishing a multidisciplinary team to evaluate system-wide FIT processes and practices; and modifying the facility's pre-printed FIT label to include the date of specimen collection.

The VISN and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes B and C). The OIG considers all recommendations open pending documented evidence for closure. The OIG will follow up on the planned actions until they are completed.

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Assistant Inspector General
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Contents

Abbreviations

CLIA	Clinical Laboratory Improvement Amendments
CRC	colorectal cancer
EHR	electronic health record
FIT	fecal immunochemical test
OIG	Office of Inspector General
PACT	patient aligned care team
QSI	Quality, Safety, and Improvement
USPS	United States Postal Service
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations that more than 400 patient colorectal cancer (CRC) screening tests at the Phoenix VA Health Care System (facility) in Arizona had been stored in a non-VA warehouse for more than 30 days.

Background

The facility is part of Veterans Integrated Service Network (VISN) 22 and includes the Carl T. Hayden VA Medical Center in Phoenix and 10 outpatient clinics located throughout central Arizona.[1] From October 1, 2021, through September 30, 2022, the facility served 116,361 patients.[2] The Veterans Health Administration (VHA) classifies the facility as a 1a, highest complexity facility.[3] The facility provides healthcare services including primary care, long-term care, and specialty medicine such as surgery, neurology, oncology, dentistry, geriatrics, nutrition, psychiatry, and physical medicine and rehabilitation.

Colorectal Cancer and Screening

CRC, a cancer located in the colon or rectum, is the third leading cause of cancer death for both men and women in the United States. In 2023, it is estimated that 52,550 individuals within the United States will die of CRC.[4] Most CRCs arise from precancerous growths (polyps) that form on the inner lining of the colon or rectum. Most polyps are non-cancerous (benign), but over time, some can develop into cancer (malignant). Early detection and removal of polyps can prevent cancer from forming and promote a full recovery from benign or precancerous polyps. As CRC "rarely causes symptoms in its early stages, screening for the disease is important."[5]

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[1] "VA Phoenix Locations," accessed February 2, 2023, https://www.va.gov/phoenix-health-care/locations/. Facility community-based outpatient clinics include locations in Gilbert, Phoenix, Scottsdale, Payson, Show Low, Globe, Mesa, and Surprise, Arizona.

[2] "Trip Pack – Operational Statistics Table FY 2023 through January," VHA Support Service Center (VSSC), accessed February 14, 2023, https://reports.vssc.med.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fMgmtReports%2fPocketCard%2fTripPack_OperationalStatisticsTable&rs:Command=Render. (This web page is not publicly accessible.)

[3] VHA Office of Productivity, Efficiency, and Staffing (OPES), "Fact Sheet Facility Complexity Model," November 7, 2022. "The model rates facilities as 1a, 1b, 1c, 2 or 3, with facilities rating 1a being the most complex and those rated 3 the least complex."

[4] Siegel, RL, Miller, KD, Wagle, NS, Jemal, A. "Cancer statistics, 2023," *CA Cancer J Clin*. 2023; 73(1): 17-48. https://doi.org/10.3322/caac.21763.

[5] VA, Veterans Health Library, "Colorectal Cancer Screening," accessed February 14, 2023, https://www.veteranshealthlibrary.va.gov/RelatedItems/142,87081_VA.

Although most often diagnosed in adults ages 65 to 74, an estimated 10.5 percent of new CRC cases occur in individuals younger than age 50. In 2021, the US Preventive Services Task Force updated their recommendation to begin CRC screening in asymptomatic, average-risk adults at the age of 45 instead of the previously recommended age of 50.[6] CRC screening tests, recommended by the US Preventive Services Task Force, are categorized as either stool-based or direct visualization tests. The fecal immunochemical test (FIT) is a stool-based test that detects the presence of blood in the stool that may be indicative of colon polyps or cancer; it is repeated annually. The colonoscopy is a direct visualization test that uses a camera to visualize the inside of the colon; it is repeated every 10 years. Each test has unique risks and benefits to consider when determining the best screening test for each patient.[7]

Allegations and Related Concerns

On September 9, 2022, the OIG received a complaint alleging that more than 400 FITs were delivered to the facility in June 2022 after being held in a non-VA warehouse for more than 30 days because of unpaid postage bills.[8] The OIG opened the inspection to assess the merit of the allegations, specifically to determine whether there was a

- delay in the receipt of more than 400 patient FITs,
- failure to protect the personal identifying information of affected patients, and
- delay in the affected patients receiving further evaluation and care, when warranted.

During the course of the inspection, the OIG identified additional concerns related to

- proper handling and recording of FIT specimens,
- ensuring FIT specimen stability prior to processing, and
- missed opportunities to address specimen collection dates.[9]

[6] US Preventive Services Task Force, "Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement," *JAMA.* 2021;325(19):1965–1977, https://doi.org/10.1001/jama.2021.6238.

[7] US Preventive Services Task Force; Veterans Health Library.

[8] The complainant reported 408 FITs. During the inspection, facility documentation indicated the number to be either 406 or 407. The OIG reviewed the data but could not clearly discern the number. The OIG refers to the number of FITs as 406 throughout this report based on initial documentation.

[9] *Merriam-Webster.com Dictionary*, "specimen," accessed February 14, 2023, https://www.merriam-webster.com/dictionary/specimen; *Merriam-Webster.com Dictionary*, "sample," accessed February 14, 2023, https://www.merriam-webster.com/dictionary/sample. In this report, the OIG uses the term "specimen" to indicate the stool sample collected in the FIT vial. The terms specimen and sample are often interchangeable.

Scope and Methodology

The OIG initiated the healthcare inspection on November 9, 2022, and conducted an on-site inspection December 12–15, 2022. The OIG conducted virtual and on-site interviews from November 23, 2022, through February 9, 2023, and an additional interview on April 4, 2023, with outpatient nursing leaders to clarify and observe specimen processes and labeling.

The OIG team interviewed the VHA National Executive Director and Associate Director for the Pathology and Laboratory Medicine Services Program Office; VISN 22 Chief of Pathology and Laboratory Medicine Services; facility Chief of Staff; and leaders in primary care, logistics, pathology and laboratory, and Quality, Safety, and Improvement (QSI).[10] In addition, the OIG conducted interviews with other staff knowledgeable about the events and related processes, including a patient aligned care team (PACT) provider and nurses, and laboratory staff.[11] The OIG conducted an exit brief with the interim Facility Director and key facility and VISN 22 leaders on December 15, 2022, as well as follow-up virtual meetings with key leaders on January 11 and April 27, 2023.

During the on-site inspection, the OIG observed selected processes and procedures within the mail room, laboratory, and a primary care clinic. The OIG reviewed relevant VHA policy and guidance documents, facility policies and procedures, select patients' electronic health records (EHRs), and related professional literature, standards, and journals.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a

[10] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016. The VHA National Director of the Pathology and Laboratory Medicine Services Program Office provides oversight and guidance to ensure the quality of laboratory services.

[11] VHA Handbook 1101.10(1), *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014, amended May 26, 2017. VHA defines PACT as "a team of health care professionals that provides comprehensive primary care in partnership with the patient (and the patient's personal support person(s)) and manages and coordinates comprehensive health care services consistent with agreed upon goals of care."

specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

VHA recognizes that "the lengthy preclinical phase of CRC development allows opportunities for clinicians to successfully detect cancer and intervene at a curable or treatable stage through screening."[12] To optimize these opportunities, it is VHA policy to recommend CRC screening to average-risk patients ages 45 through 75, in accordance with VHA clinical preventive services guidance and in alignment with the US Preventive Services Task Force recommendations.[13] VHA's preferred method of CRC screening for patients at average risk for CRC is the FIT.[14] Most often, patients collect a stool specimen at home using a FIT kit provided by their healthcare provider and send the specimen to a laboratory for testing.[15] See figure 1 for FIT kit contents.

[12] VHA Directive 1015, *Colorectal Cancer Screening*, April 3, 2020, amended November 22, 2022. The directive was amended after the events discussed in this report; however, neither the language nor the content relevant to and included in this report was changed.

[13] VHA Directive 1015. VHA defines patients at an average risk for CRC as "those with neither a family history of CRC nor other risk factors or symptoms that warrant surveillance or diagnostic colonoscopy;" VA, "VHA Preventive Care Program," VHA National Center for Health Promotion and Disease Prevention (NCP), accessed February 27, 2023, https://vaww.prevention.va.gov/VHA_Preventive_Care_Program.asp. (This web page is not publicly accessible.) VHA Clinical Guidance Statements for Preventive Services "are intended to provide VHA clinicians. . . a one-stop source for guidance on clinical preventive services and resources in VHA" with the goal of providing "a coordinated and evidence-based approach to policy-making."

[14] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) (11), "Implementation of Programmatic Mailed Fecal Immunochemical Testing (FIT) for Colorectal Cancer Screening (VIEWS 9018428)," memorandum to VISN Directors, VISN Chief Medical Officers, VISN Integrated Clinical Community Leads for Specialty Care, Diagnostics and Primary Care, December 20, 2022.

[15] Veterans Health Library. In this report, the OIG uses the term "specimen" to indicate the stool sample collected in the FIT vial. The terms specimen and sample are often interchangeable.

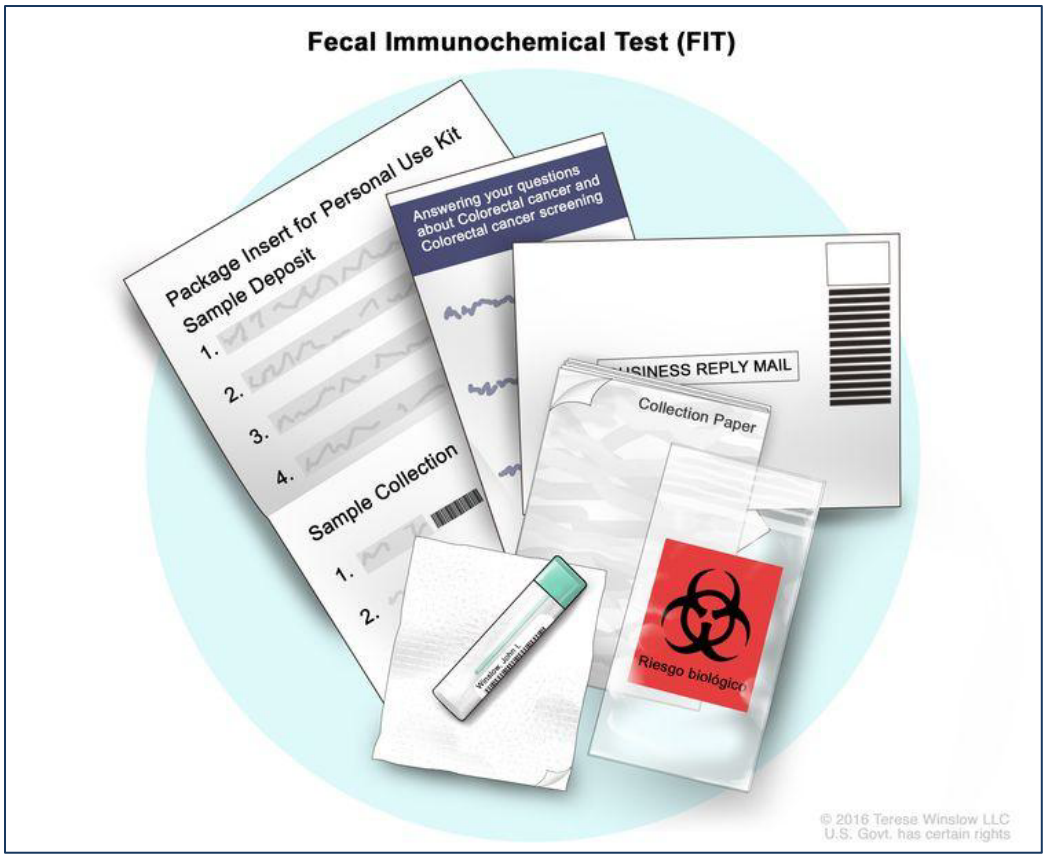

Figure 1. *The contents of a FIT kit. The OIG verified that the FIT kit includes instructions for collecting the stool sample; collection paper; a collection tube (vial) to place the stool specimen once collected; a red plastic hazard bag in which to place the vial; and a business reply mail envelope used to return the specimen to the designated laboratory for processing.*
Sources: National Cancer Institute, Colorectal Cancer Screening (PDQ), Patient Version®, OIG interview, and observation. [16]

At the facility, staff explained that primary care providers place an order for a FIT and nurses or laboratory staff distribute the FIT kit to the patient. The patient collects the stool specimen at home using the enclosed manufacturer's instructions and mails the specimen to the facility's main laboratory in the business reply envelope provided. The United States Postal Service (USPS) delivers mail containing patient FIT specimens to the facility. According to policy, facility mailroom staff sort and distribute incoming mail to the identified department.[17]

The FIT specimen is time sensitive. According to FIT manufacturer's guidelines and facility policy, once collected and placed in the vial, the specimen is stable for 15 days at room

[16] "Colorectal Cancer Screening-Patient Version," National Cancer Institute, accessed November 14, 2022, https://www.cancer.gov/types/colorectal/patient/colorectal-screening-pdq.
[17] MCP 90-10, *Mail Operations,* May 11, 2021.

temperature or 30 days when refrigerated.[18] Processing specimens outside of the stability period compromises both the integrity of the specimen and the validity of the FIT results.

1. Delayed Receipt of Patient FITs Due to Unpaid Postage Bill

The OIG substantiated that 406 patient FITs were held in a USPS station for approximately 60 days due to an unpaid postage bill by the facility. The delay resulted in laboratory staff's inability to process 403 (99 percent) of the patient FITs because the specimens were outside the stability period.[19]

The OIG team interviewed the chief of logistics and the logistics supervisor, who oversee facility mailroom operations and staff, to gain a better understanding of the backlog of mail. The logistics supervisor stated that on June 2, 2022, a USPS employee called to inform the logistics supervisor facility mail was being held at a USPS station because of an unpaid postage bill. The logistics chief and supervisor explained they learned the mail had not been delivered because the facility had not paid the USPS annual fee for business reply mail due in April of each year. As a result, USPS had not delivered the business reply mail containing the patient FITs to the facility for an estimated 60 days. The logistics supervisor shared that the USPS employee who reported the incident had been temporarily detailed to the station and became concerned about the mail after recognizing that business reply envelopes were addressed to the facility and may be important. Once apprised of the situation, the logistics supervisor reported paying the bill the same day and setting up automatic payments to prevent future unpaid bills.

The logistics supervisor told the OIG that once the payment was made, USPS delivered the mail to the facility and the laboratory manager reported the mail containing specimens was delivered to the laboratory. However, by the time the laboratory received the 406 patient FITs, facility staff found 403 (99 percent) of the specimens were outside of the 15-day stability period and could not be processed.

During an interview with the OIG, the chief of logistics explained that the supervisor with oversight of the mailroom resigned at the end of March or in early April 2022 and responsibility for the mailroom was reassigned to a new logistics supervisor. The chief of logistics acknowledged that operational knowledge was lost during the transition. Similarly, the logistics supervisor reported not being aware of the bill or the systems used to pay postage bills due to

[18] Polymedco, *OC-Auto® Micro 80 iFOB Test*, June 2, 2016. MIC 1013 OC-80, *Auto Micro Fecal Immunochemical Test (FIT)*, July 6, 2018, reviewed and approved April 8, 2022. For the purposes of this report, a specimen is considered stable when its structure remains unchanged. Changes in conditions, such as temperature and time, may affect the stability of the specimen and the outcome of the lab result. Due to the nature of the test involving patients collecting specimens at home and mailing FITs to the facility, stability cannot be assured beyond room temperature conditions; therefore, the OIG considers specimens to be stable for 15 days.

[19] The QSI program manager provided documentation to the OIG that 3 of the 406 FITs were processed. The OIG did not independently validate the provided information.

being new to the position, and not receiving guidance or training from the prior supervisor. The logistics supervisor questioned mailroom staff and was informed that the prior supervisor had taken sole ownership of the payment processes and had not involved other mailroom staff. To prevent the situation from reoccurring, the logistics supervisor reported involving the lead mail clerk in mail billing processes, automatic payments, and tracking funds. In addition, the chief of logistics reported that contact information for key staff was exchanged between the facility and USPS.

The OIG concluded that logistics leaders' failure to pay a USPS postage bill resulted in delayed delivery of 406 patient FITs to the facility. The OIG found that a person-dependent payment process, change in supervisors, and failure to transfer key knowledge regarding USPS postage bills and payment processes resulted in the breakdown. Prior to this inspection, the chief of logistics and logistics supervisor implemented necessary changes to prevent future occurrences. Although the billing issue was resolved, 403 FIT specimens were determined to be outside of the stability time frame and could not be processed.

Questionable Practices: Accession and Determination of Specimen Stability

The OIG determined that 403 FIT specimens, found to be outside of the 15-day stability period, were not accessioned according to laboratory policy, and non-laboratory staff made decisions regarding the specimens' stability. The OIG found that in an effort to ensure the 406 FIT specimens were acted upon timely, QSI staff reviewed and recorded available patient information from the FIT vials, including the specimen collection date; however, laboratory staff did not enter the information in the patients' EHRs. In addition, the OIG found the facility acting chief of pathology and laboratory medicine was unaware of who handled the FIT specimens, did not have oversight of the process, and could not ensure FIT testing was completed and accurately recorded.

Facility policy describes accessioning as the process of receiving, inspecting, and recording or scanning specimens into a patient's EHR. Per policy, all specimens come through the laboratory's central processing area where laboratory staff are responsible for ensuring each specimen meets requirements for testing. Laboratory staff record each specimen into the patient's EHR by order number and assign an accession number. A specimen that cannot be processed for any reason must be canceled or deleted, with "an explanation (comment) of why the test(s) is not being processed and tested."[20] See appendix A, visual image of the facility's FIT processing.

[20] SAQ 1010, "Accessioning and Processing of Laboratory Specimens," April 26, 2022.

VHA requires laboratories to meet the requirements of the Clinical Laboratory Improvement Amendments (CLIA).[21] CLIA requires the use of only qualified staff "in performing and carrying out its laboratory examinations and other procedures."[22] Per VHA policy, the chief of pathology and laboratory medicine is responsible for the oversight of "all laboratory testing, regardless of complexity level or where it is performed."[23] Additionally, the chief of pathology and laboratory medicine "is responsible for ensuring. . . FIT testing is completed and accurately recorded" in accordance with VHA guidelines.[24]

The former interim chief of QSI (former chief of QSI) told the OIG team of becoming aware of the incident after receiving a joint patient safety report about the delayed receipt of a large number of patient FITs.[25] The former chief of QSI contacted the laboratory manager who explained the FIT specimens were being stored in the laboratory's refrigerator and had not been accessioned or processed. Per the former chief of QSI, the laboratory manager reported that there were not enough laboratory staff to process the 406 FITs promptly. The former chief of QSI reported having "a great sense of urgency" to resolve the matter and coordinated assistance from staff within the QSI department.

To guide QSI staff in sorting the FIT specimens, the laboratory manager emailed the former chief of QSI a copy of the FIT package insert that included information about specimen stability.[26] Staff told the OIG that QSI staff were provided instructions for handling the FITs, including removing the vials from the outer envelopes and plastic biohazard bags, recording the available patient information, and sorting by the date of collection to determine if the specimen was within the stability period.

The QSI staff identified and recorded a total of 406 business reply envelopes containing FIT specimens and informed the OIG that 3 specimens were within the required 15-day stability time frame. The laboratory manager told the OIG of being present throughout the process and providing technical oversight; however, QSI staff's recollection of the laboratory manager's presence varied from little to no oversight during the process.

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[21] VHA Handbook 1106.01. The CLIA of 1988 are amendments to the Public Health Services Act (Title 42 United States Code 263a (42 U.S.C.§263a)) for the management and oversight of clinical "laboratories that perform testing used in the diagnosis, treatment, and prevention of disease in patients." Public Law 102-139, Sec. 101(a), passed by Congress in 1991, exempts VHA from CLIA and "requires VA laboratories to meet the requirements of CLIA, but left the enforcement and oversight of the regulations to VA."

[22] Centers for Disease Control and Prevention, Clinical Laboratory Improvement Amendments (CLIA) Law and Regulations, Clinical Laboratory Improvement Amendments, 42 U.S.C.§263a.

[23] VHA Handbook 1106.01.

[24] VHA Directive 1015.

[25] VHA National Center for Patient Safety, *JPSR Guidebook*, December 2022. "The Joint Patient Safety Reporting (JPSR) System is the [VHA] patient safety event reporting system and database."

[26] Polymedco.

The former chief of QSI reported informing the Facility Director and Chief of Staff of the delayed FITs by email. The OIG reviewed the email communication and noted the former chief of QSI informed the Facility Director and Chief of Staff of the incident, provided the tallied number of FITs, and questioned if all the specimens should be processed. The Chief of Staff responded to the email stating that a plan to rescreen the affected patients had been developed. As part of the rescreening plan, the PACT coordinator reported following up with affected patients to resubmit FITs using existing provider orders when possible. Consequently, through interviews and documentation, the OIG determined that laboratory staff did not accession or process the 403 specimens and did not document the FITs in patients' EHRs.

The OIG learned that, although aware of the delayed FITs, neither the facility acting chief of pathology and laboratory medicine nor the VISN 22 Chief of Pathology and Laboratory Medicine Services were aware that non-laboratory staff handled the delayed FIT specimens and that the specimens were not accessioned. The laboratory manager reported informing the acting chief of pathology and laboratory medicine of the incident. However, during an interview, the acting chief of pathology and laboratory medicine reported being unaware that non-laboratory staff completed these processes, and was unsure if QSI staff's involvement was a reason for concern or a violation of standards. The VISN 22 Chief of Pathology and Laboratory Medicine Services also reported to the OIG team being unaware that the FIT specimens were handled by non-laboratory staff, and emphasized that specimens should be opened and assessed by the laboratory staff who have training and competencies needed.

As the facility acting chief of pathology and laboratory medicine and VISN 22 Chief of Pathology and Laboratory Medicine Services had different responses regarding the appropriateness of non-laboratory staff handling and dispositioning the delayed FIT specimens, the OIG sought clarification from VHA's Pathology and Laboratory Medicine Program office. The VHA Associate National Director for Pathology and Laboratory Medicine told the OIG that specimens should be visually inspected and assessed for stability in an area supervised by certified testing personnel and that "it may not be fully prohibited that a non-laboratory personnel would do that kind of task," but added that competency must be demonstrated per regulatory (CLIA) requirement. The VHA Associate National Director for Pathology and Laboratory Medicine reported that although the decision to not accession the 403 specimens was not standard procedure or recommended, given the circumstances, it was understandable how the decision could have been made.

The OIG concluded that in an effort to ensure the 406 FIT specimens were acted upon timely, non-laboratory QSI staff reviewed the FITs, recorded available patient information, and found 403 specimens were outside of the 15-day stability period. These specimens were not accessioned or recorded with results in the patients' EHRs as required by facility policy. Neither the facility acting chief of pathology and laboratory medicine nor the VISN 22 Chief of Pathology and Laboratory Medicine Services were aware of the processes and decisions

regarding the handling and disposition of the FIT specimens. Consequently, the acting chief of pathology and laboratory medicine could not ensure the FITs were accessioned properly. Without accessioning, providers may have been unaware that a patient's specimen was received but may have not been processed due to instability of the specimen.

Alleged Failure to Protect Patient Identifying Information

The OIG did not substantiate that patients' personally identifiable information from FITs, including specimen vials, was not properly disposed of or protected. The OIG found that staff disposed of items containing patients' personally identifiable information.

VHA requires facility staff to "ensure the security and confidentiality of" patients' personally identifiable information.[27] Waste that "may be contaminated by blood, body fluids, or. . . human. . . waste" is considered regulated medical waste and must be disposed of accordingly, such as in biohazard bags and bins, and treated.[28]

In interviews with the OIG, staff who assisted with the 406 FITs reported placing envelopes and bags containing patients' information into biohazard receptacles. During the site visit, the OIG observed the area where the sorting had occurred and noted biohazard receptacles were used for waste. The laboratory manager told the OIG of understanding that the contents of the biohazard receptacles were incinerated. The OIG concluded that staff took the appropriate measures to ensure the information was protected.

2. Further Evaluation and Care for Affected Patients

The OIG did not substantiate a delay in further evaluation and care for the patients whose FITs were outside of the stability period and could not be tested. The OIG found that once patient FITs were received, facility staff acted quickly to identify the patients who were affected, developed a reasonable follow-up plan, and took appropriate measures to ensure affected patients were screened or further evaluated for colorectal cancer.

The associate chief of staff for primary care informed the OIG that, after facility staff found the vast majority of the FIT specimens were not stable for testing, they began reviewing patient

[27] VHA Directive 1605.01, *Privacy and Release of Information,* August 31, 2016; VHA Directive 6066, *Protected Health Information (PHI) and Business Associate Agreements Management,* September 2, 2014. Personally identifiable information (PII) "is any information about an individual that can be used to distinguish or trace an individual's identity, alone, or when combined with other information which is linked or linkable to a specific individual, such as: name, social security number, date and place of birth, mother's maiden name, telephone number."

[28] VHA Directive 1850.06, *Waste Management Program*, July 22, 2022; VA, *EPS Comprehensive Guide on Regulated Medical Waste (RMW)*, February 17, 2022, accessed January 18, 2023, http://vaww.hefp.va.gov/resources/eps-comprehensive-guide-regulated-medical-waste. (This website is not publicly accessible.)

records to determine which patients needed to be rescreened for CRC. Per the associate chief of staff for primary care, the PACT coordinator was "instrumental" in implementing a plan to track and follow up with patients who needed a repeat FIT. On June 15, 2022, the associate chief of staff for primary care sent an informational email notifying primary care providers that more than 400 patient FITs were delayed and advising that no action was needed from the providers at that time.

The OIG team interviewed the PACT coordinator and learned that after QSI staff developed an initial list of patients, Primary Care Services staff were notified and began developing a plan for the affected patients. The PACT coordinator reported conducting EHR reviews to ensure patients were accurately identified and to determine which patients needed to be rescreened for CRC. After excluding patients who did not need repeat FITs, the PACT coordinator found that 369 patients needed to be rescreened for CRC.[29] On June 27, the PACT coordinator, and a small group of QSI and PACT nursing staff, sent a new FIT kit to each of the 369 patients along with a letter explaining that the original FIT submitted could not be processed and requesting the patient complete and return a new FIT.

During the OIG site visit in mid-December 2022, the OIG team learned that follow-up efforts for affected patients were well underway; these efforts continued throughout December. As of December 14, the PACT coordinator reported that 228 of the 369 patients (62 percent) had completed a FIT and returned the specimen to the facility. Per the PACT coordinator, 128 patients had neither returned a FIT specimen nor underwent a colonoscopy as of December 23. In response, PACT nursing staff mailed a new FIT kit and letter on December 27 to the remaining 128 patients.

The PACT coordinator reported that, as of January 25, 2023, 95 of the affected 369 patients (26 percent) were still in need of a colorectal cancer screening. The PACT coordinator reported the facility would continue to monitor these patients and planned to send an additional follow-up letter and FIT at the end of March 2023 to patients who had not yet completed a colorectal cancer screening at that time. The PACT coordinator, who continued to track these patients, updated the OIG team and reported that as of May 8, 2023, 47 of the affected patients had "not responded to requests for replacement FIT kit completion."

The OIG concluded that primary care leaders' and staff's plan to follow up on the delayed FITs and their efforts to ensure patients received further evaluation and care were timely and thorough.

[29] The PACT coordinator reported to the OIG that the patients excluded from the FIT follow-up efforts were those who did not need a repeat FIT. Reasons for exclusion included patients who had already completed another FIT, patients whose specimens were within the stability period and could be processed, patients who had died of conditions unrelated to CRC, duplicates (patients who had completed two tests), and patients who had scheduled colonoscopies.

OIG Patient Review: No Adverse Clinical Outcomes Identified

The OIG team conducted an independent review of selected patients, identified by facility staff as having died since the submission of the initial FIT in the spring of 2022, as well as those patients whose repeat FIT was positive, to determine whether patients experienced adverse clinical outcomes related to a delay in CRC screening.[30] Specifically, the OIG reviewed the EHRs of 12 deceased patients and 19 patients with positive FIT results.

The OIG did not identify an adverse clinical outcome related to the delay in CRC screening for any of the 31 patients reviewed. The OIG determined that the 12 patients' deaths were not impacted by a delay in CRC screening and were unrelated to CRC. Additionally, the OIG determined the 19 patients whose repeat FIT results were positive did not have an associated adverse clinical outcome.

The OIG reviewed the 19 patients' EHRs to ensure patients were notified of their positive CRC screening results and were offered and received further evaluation and treatment, when warranted and per the patient's preference. With the exception of two patients, the OIG found the PACT coordinator and team completed reasonable follow-up efforts with the patients. The OIG did not find (1) evidence that one patient had been informed of a positive FIT result, or (2) a documented plan for another patient who was informed of a positive FIT result. To ensure these patients received timely follow-up, the OIG team held a virtual meeting with facility leaders on January 11, 2023, to share concerns regarding the two patients, and discussed a third patient who had declined a colonoscopy but may have benefited from further outreach. On January 30, facility leaders provided a summary of the follow-up actions taken and the status of the three patients; the OIG team reviewed and verified the information in each patient's EHR and agreed no additional follow-up actions were needed.

The OIG concluded there were no identifiable adverse clinical outcomes for any of the 31 patients reviewed. Further, the OIG found that follow-up efforts on the three patients discussed with leaders were completed.

3. Failure to Ensure Specimen Stability for Processing

The OIG determined that laboratory staff's FIT processing practices failed to consistently ensure FIT specimen stability by confirming that specimens were collected and processed within the 15-day stability period. Failure to ensure specimen stability compromises the validity of the test

[30] Within the context of this report, the OIG considered adverse clinical outcomes to be defined as death, hospitalization, or significant change in the status of a patient's health, that in the OIG's assessment, may have been preventable if a positive result from the CRC screening had been identified when the patient originally returned the FIT specimen in the spring of 2022.

results, increasing the likelihood of false-negative results.[31] The OIG found the laboratory manager and staff

- lacked knowledge and clarity about FIT specimen stability and storage requirements;
- processed FIT specimens regardless of whether the date of collection was recorded or known, and at times;
- recorded the date the specimen was received or processed as the date of collection in the patient's EHR, when the actual date of collection was not known.

Facility policy outlines the laboratory process steps required when accessioning and processing specimens. Specifically, laboratory staff are responsible for inspecting "the specimen integrity and labeling," which includes ensuring the

- specimens "have the test order number, date and time of collection."
- "test is valid and collected in the proper container, received under the proper transport and storage conditions and that specimen stability requirements are met."[32]

The facility's FIT-specific procedure details the specimen and specimen storage requirements, which emphasize that "fresh stool is required. . . due to stability of hemoglobin [blood]" and states specimens "may be stored at room temperature for up to 15 days."[33] A delay between the date and time the specimen is collected and when it is delivered and processed in the laboratory decreases the test performance, as over time at room temperature, the hemoglobin in the stool specimen degrades. This increases the likelihood of false negatives.[34]

When laboratory staff find that a specimen is not acceptable, facility policy provides direction on rejecting the specimen.[35] "Every order that has an accession number and cannot be completed for whatever reason must be either canceled or deleted, but every test MUST have an explanation (comment) of why the test(s) is not being processed and tested."[36]

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[31] L.G.M. van Rossum, A.F. van Rijn, M.G.H. van Oijen, P. Fockens, R.J.F. Laheij, A.L.M. Verbeek, J.B.M.J. Jansen, and E. Dekker (2009), "False negative fecal occult blood tests due to delayed sample return in colorectal cancer screening," *International Journal of Cancer*, 125: 746-750, 2009, https://doi.org/10.1002/ijc.24458; National Cancer Institute, "false-negative test result," accessed June 4, 2023, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/false-negative-test-result. A false-negative test result "indicates that a person does not have a specific disease or condition when the person actually does have the disease or condition."

[32] SAQ 1010.

[33] MIC 1013 OC-80.

[34] Van Rossum, van Rijn, van Oijen, Fockens, Laheij, Verbeek, Jansen, and Dekker, "False negative fecal occult blood tests due to delayed sample return in colorectal cancer screening," 2009.

[35] SAQ 1010.

[36] SAQ 1010.

During the inspection, the OIG team learned that when QSI staff reviewed and collected patient information from the delayed FITs, patients did not record the collection date on 351 of the 406 specimens (86 percent). Due to the significant number of FITs that did not have the date the patient collected the stool specimen, the OIG became concerned about the prevalence of this omission in all FIT specimens received and processed at the facility.

The OIG conducted interviews and exchanged correspondence with the laboratory manager and staff and learned that the laboratory commonly received FIT specimens without a collection date. In an email, the laboratory manager reported that "approximately 25 [percent] of the collected FIT specimens that the lab[oratory] receives via mail do not have a specimen collection date documented by the patient." Two laboratory medical technologists (technologists), who regularly processed FITs, reported a much higher occurrence. One technologist informed the OIG team that more than 75 percent of FIT specimens do not have a collection date, and another technologist estimated that 90 percent do not have a collection date. The technologists' estimates of FIT specimens received without a collection date (75–90 percent) were in alignment with QSI staff finding 86 percent of the 406 delayed FITs did not have collection dates.

The OIG questioned the laboratory manager about the stability of FIT specimens, the process of receiving and processing FITs, and related practices. The laboratory manager stated, multiple times, that a FIT specimen is stable for 30 days at room temperature. The laboratory manager explained that laboratory staff refer to the test's order date when a FIT specimen does not have a collection date. When the order date is within 30 days, laboratory staff determine the specimen is stable for processing. When the specimen is outside 30 days, the laboratory manager reported that staff assign a lab order number to accession the specimen; however, rather than test the specimen, they add a comment that the specimen exceeds stability.[37]

Two days later, after recognizing the discrepancy between the manufacturer's 15-day specimen stability time frame and the laboratory manager's report of 30 days, the OIG requested clarification of the laboratory manager's understanding of FIT specimen stability. In an email response, the laboratory manager provided an excerpt from the manufacturer's guidelines, which stated the specimen was stable "up to 15 days." The OIG noted the information provided regarding the specimen stability time frame contradicted the earlier responses the laboratory manager provided when interviewed.

[37] When interviewed, one technologist relayed that when processing a FIT specimen that is outside of the 30 days, laboratory staff may run the test and attach a comment to the result stating that the specimen exceeded stability.

During interviews, the OIG noted that technologists' knowledge of and practices related to FIT specimen stability, although similar to those initially reported by the laboratory manager, were inconsistent with related facility policies and procedures.[38] Specifically, technologists

- referred to the FIT specimen stability time frame as 30 days instead of 15 days, and referenced using 30 days from the FIT order date to gauge specimen stability when no collection date was provided; and
- reported processing FIT specimens that did not have a collection date when there was an indication, such as order date, the specimen was within the 30 day time frame.

In addition, one technologist relayed processing FITs with order dates from three or six months prior, citing that the specimen may have been collected later.

During a demonstration of laboratory FIT processes within a patient's EHR, a technologist reported that if a specimen did not have a collection date, laboratory staff may enter the date the specimen was processed as the collection date. The OIG viewed examples of this practice during the demonstration, noting that the date of collection was recorded as either the same day or the day prior to the date processed. The technologist later clarified that when laboratory staff enter "'U' for an unknown collection date/time" in a patient's EHR, the computer system "will automatically give the current date time/received date and time as the collection time."

During an interview, the acting chief of pathology and laboratory medicine reported the understanding that the laboratory would reject the specimen if there was no collection date, and clarified that it is the collection date, not the order date, that is important in determining the stability of the specimen. The VISN 22 Chief of Pathology and Laboratory Medicine Services stated that the order date should not be used to determine stability as it does not correlate with the collection date, adding that if the collection date was not documented, the specimen should be accessioned but not processed.

The OIG concluded that laboratory staff routinely processed FIT specimens outside of the 15-day stability period, calculated the specimen stability date as 30 days from the order date, and at times, recorded the collection date as the date they received or processed the specimen.

Due to the significance of this concern, the OIG team spoke with VISN and facility leaders on April 27, 2023. The OIG informed leaders that laboratory staff were improperly processing FIT specimens, explained the circumstances that led to the finding, and discussed the potential impact on patients who may have received false-negative test results. Although a formal finding and recommendation would be forthcoming, the OIG asked VISN and facility leaders to begin reviewing laboratory staff's FIT processing practices and taking actions to ensure FIT specimen stability standards were met before processing FIT specimens. Leaders were unaware of the

[38] MIC 1013 OC-80. Gen-PG 1058, Acceptance and Performance of Laboratory Orders/Specimens, May 14, 2015.

processing issues brought forward, receptive to and concerned about the information received, and eager to discuss immediate actions.

Contributing Factor: Pre-Printed FIT Labels

The OIG found that PACT and laboratory staff's use of pre-printed, patient-specific FIT labels contributed to the omission of collection dates on the FIT vials and may have contributed to laboratory staff's practice of referencing the test order date when determining specimen stability. Specifically, PACT staff placed the pre-printed labels that did not include a space for the collection date over the original manufacturer's FIT label. Further, a lack of PACT awareness of the importance of the collection date in determining a specimen's stability contributed to the ongoing use of the pre-printed labels and lack of, or inconsistent, guidance given to patients.

The laboratory manager reported that Primary Care Services staff place a pre-printed label containing the order number, patient's name, and other demographics on the vial when distributing a FIT. Laboratory staff reported that the use of pre-printed labels had mitigated concerns with handwritten label legibility. During an interview, the PACT coordinator and chief nurse of ambulatory care demonstrated the process for labeling the FIT vial, which included entering the patient-specific information into the patient's EHR, populating a pre-printed, patient-specific label, and placing the pre-printed label over the existing manufacturer's label. During the demonstration, the OIG noted, and the PACT coordinator confirmed, the pre-printed labels included the order date but did not include collection dates or a space for patients to indicate the collection date.

The OIG observed patients' vials in the laboratory and photos of vials provided by the laboratory manager and noted that, although FIT vials with the manufacturer's labels had a space for patients to complete the collection date, the pre-printed label was without a space for the collection date and placed over the manufacturer's label. The OIG reviewed VHA guidance on FIT processes and noted an example of a pre-printed, patient-specific label was provided, which included a prompt and space for date of collection.[39] See figure 2 for examples of labels.

[39] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) (11), "Implementation of Programmatic Mailed Fecal Immunochemical Testing (FIT) for Colorectal Cancer Screening (VIEWS 9018428)," memorandum.

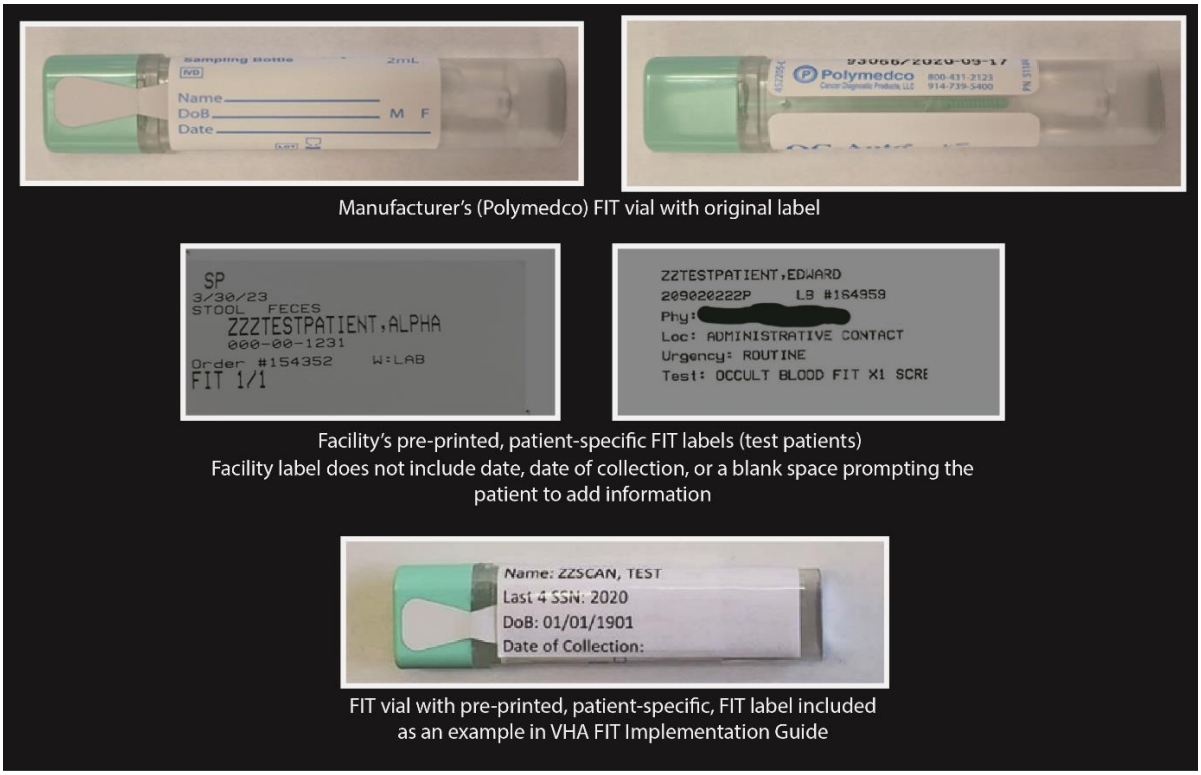

Figure 2. *Manufacturer's and facility vial labels.*
Sources: Photos taken by the OIG and facility staff and memorandum "Implementation of Programmatic Mailed Fecal Immunochemical Testing (FIT) for Colorectal Cancer Screening." The OIG team referred to the implementation memo as "VHA FIT Implementation Guide."[40]

During the on-site inspection, the OIG also observed inconsistencies in patient education provided by primary care clinic staff related to collection, labeling, and return of FITs. Additionally, the OIG found that, in general, nurses and staff did not educate patients to record the date of collection on the specimen or to return FITs timely. The PACT coordinator reported the facility did not have a standard operating procedure or facility-created written guidance related to patient education that staff should provide when distributing the FIT. A technologist noted the process could improve if patients received more instruction.

The OIG concluded that a lack of PACT awareness of the importance of the collection date in determining the specimen's stability contributed to the ongoing use of the pre-printed labels and lack of, or inconsistent, guidance given to patients. When the date of collection is not recorded on returned specimens, laboratory staff cannot accurately determine the specimen's stability, and test results may not be reliable.

[40] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) (11), "Implementation of Programmatic Mailed Fecal Immunochemical Testing (FIT) for Colorectal Cancer Screening (VIEWS 9018428)," memorandum.

Facility Leaders Missed Opportunities to Address Specimen Collection Dates

The OIG determined that facility and service line leaders missed opportunities to evaluate and resolve identified FIT labeling issues that were indicative of broader laboratory FIT processing failures. Specifically, the OIG found facility leaders did not address omitted collection dates despite QSI staff finding that 86 percent of FIT specimens did not have a collection date. Given the magnitude and clinical significance of this issue, the OIG would have expected leaders to evaluate the frequency and cause of the omission for all FITs and the impact on either specimen rejection rates or compromised test results due to processing specimens outside of the stability period.

Further, the OIG learned the issue was not new to the facility. In 2020, facility leaders identified concerns with omitted collection dates and the inability to determine specimen stability following delayed delivery of 325 patient FITs. However, the OIG found actions put into place at that time did not resolve the underlying issue and may have inadvertently contributed to the 2022 volume of FIT vials without collection dates.

High reliability organizations have a goal of achieving "'zero harm' in an environment where accidents are expected due to complexity or risk factors."[41] One of the principles of a high reliability organization is a "reluctance to simplify" complex concerns, which encourages an investigation to identify the root cause(s) of a problem.[42]

The OIG found that upon the discovery of the delayed FITs, facility and service line leaders engaged in timely corrective actions to rectify payment of the annual business reply mail fee; however, they failed to recognize the significance of and address the identified FIT label concern.[43] During the sorting of the delayed FITs, QSI staff noted a significant need to educate patients to record the date of specimen collection on the FIT vial. In an OIG interview, the former chief of QSI reported having relayed the concern to the primary care team, as the owners of the process. When the OIG asked about actions taken to address the FIT labeling concerns, the PACT coordinator reported instructing nursing staff to utilize the pre-printed FIT label and to encourage patients to complete the FIT as soon as possible. The OIG reviewed the email communication sent by the PACT coordinator to primary care nurse managers in July 2022, and

[41] VHA Directive 1026.01, *VHA Systems Redesign and Improvement Program*, December 12, 2019.

[42] VHA Directive 1026.01; "High Reliability Organization (HRO) Strategies: You May Be Doing More Than You Think," Health Quality Innovation Network, accessed April 13, 2022, https://hqin.org/high-reliability-organization-hro-strategies-you-may-be-doing-more-than-you-think/.

[43] Actions for the 2022 incident also included completion of a joint patient safety report; issue brief, with communication of the event to the VISN; and a root cause analysis. VHA Handbook 1050.01. A root cause analysis "is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

found the communication emphasized the use of the printed FIT labels but did not include guidance to encourage patients to complete the FIT timely. Additionally, although known by select service line leaders, the OIG could not find evidence that facility leaders were aware of the significance of the omitted collection dates on FIT labels and did not find action taken to evaluate the nature, frequency, or potential consequences of this issue.

The OIG learned that a similar issue occurred in July 2020 following delayed delivery of 325 patient FITs to the facility due to claims from USPS regarding an unpaid bill.[44] In an OIG interview, the Deputy Chief of Staff involved in resolving the 2020 incident recalled having several discussions with the former chief of pathology and laboratory medicine regarding the inability to determine the stability of the FIT specimens because of omitted collection dates.[45] The OIG reviewed an email sent in August 2020 by the former chief of pathology and laboratory medicine to the Deputy Chief of Staff that suggested the following actions to ensure specimen stability:

> 1. "When the PCP [primary care provider] orders the FIT test, the nurse will print the label with the order date (currently no date).
>
> 2. When the FIT card is handed over to the patient, tell the patient (orally as well as a written direction) to collect the specimen and mail it within a week. Otherwise, the patient will have to recollect the specimen.
>
> 3. When the specimen arrives at the Lab[oratory], the lab[oratory] staff will check if the order date is within 2 weeks. Otherwise reject the specimen and recommend recollection."

During the inspection, the OIG found it likely that facility staff implemented the suggestion of printing the labels to include the FIT order date, as facility FIT labels were commonly placed over the manufacturer's label. However, as noted previously, the facility's FIT labels did not include a space for the specimen collection date. The OIG did not find evidence that facility staff incorporated into practice and sustained the suggestions of educating patients to return the test within one week or rejecting the specimen and recommending the collection of a second specimen if the time exceeded two weeks.

The OIG found that, following the 2020 delayed FIT incident, facility staff implemented pre-printed labels on FIT vials and laboratory staff utilized physicians' FIT order dates to determine

[44] The OIG did not confirm USPS claims of unpaid funds. Documents reviewed by the OIG suggested there were sufficient funds in the mail account and the delayed delivery may have been the result of staffing shortages experienced by USPS at the time.

[45] During the time of this OIG review, the former chief of pathology and laboratory medicine was no longer in the position and there was an acting chief in place.

stability. These actions likely inadvertently contributed to the FIT labeling and stability concerns noted in the facility review in 2022.

The OIG concluded that facility leaders and service line leaders did not promote principles of a high reliability organization to determine all root causes and contributing factors, including those that are more complex upon the discovery of the delayed FITs. With the frequency of FIT labeling concerns identified by QSI staff, and through review of the delayed FIT specimen incidents in 2020 and 2022, the OIG would have expected facility leaders to review patterns and determine whether the patterns were indicative of a broader concern that could be addressed on a larger systems level.

Conclusion

The OIG substantiated that 406 patient FITs were held at the USPS due to an unpaid postage bill by the facility, which resulted in the inability to process and test 403 (99 percent) of the specimens received. Facility logistics staff resolved billing issues and implemented changes to prevent future occurrences of laboratory mail delays.

The OIG determined that 403 FIT specimens, found to be outside of the 15-day stability period, were not accessioned according to laboratory policy, and non-laboratory staff made decisions regarding the specimens' stability. In an effort to ensure the 406 FIT specimens were acted upon timely, QSI staff reviewed and recorded available patient information from the FIT vials, including the specimen collection date; however, laboratory staff did not enter the information (accession) in the patients' EHRs and document why specimens could not be processed.

The OIG did not substantiate that patients' personally identifiable information was not properly disposed of or protected. By disposing of sensitive patient information in the biohazard receptacles, staff took the appropriate measures to ensure the information was protected.

The OIG did not substantiate a delay in further evaluation and care for the patients whose FITs were outside of the stability period and could not be tested. Once patient FITs were received, facility staff acted quickly to identify the affected patients, developed a reasonable follow-up plan, and took appropriate measures to ensure affected patients were screened or further evaluated for colorectal cancer. No adverse clinical outcomes related to the delay in CRC screening were identified.

Laboratory staff's FIT processing practices failed to consistently ensure FIT specimen stability by confirming that specimens were collected and processed within the 15-day stability period, which compromised the validity of the test results. The laboratory manager and staff lacked knowledge and clarity about FIT specimen stability and storage requirements, processed FIT specimens regardless of whether the date of collection was recorded or known, and at times, recorded the date the specimen was received or processed as the date of collection.

Due to the significance of the FIT processing concerns that laboratory staff were improperly processing FIT specimens and the potential impact on patients who may have received false-negative test results, the OIG team spoke with VISN and facility leaders on April 27, 2023. The OIG informed leaders of these concerns and recommended that leaders begin reviewing laboratory staff's FIT processing practices and taking actions to ensure FIT specimen stability standards were met. Leaders were unaware of the processing issues brought forward, receptive to and concerned about the information received, and eager to discuss immediate actions.

The issue was not new to the facility; in 2020, facility leaders identified concerns with omitted collection dates and the inability to determine specimen stability following delayed delivery of 325 patient FITs. The OIG found that, following the 2020 delayed FIT incident, facility staff implemented pre-printed labels on FIT vials and laboratory staff utilized physicians' FIT order dates to determine stability. These actions likely inadvertently contributed to the FIT labeling and stability concerns noted in the facility review in 2022. Further, a lack of PACT awareness of the importance of the collection date in determining a specimen's stability contributed to the ongoing use of the pre-printed labels and lack of, or inconsistent, guidance given to patients.

Facility and service line leaders missed opportunities to address and resolve FIT labeling issues. Despite QSI staff finding that 86 percent of the delayed FITs did not have a collection date, leaders did not further evaluate FIT labeling issues that were indicative of broader laboratory FIT processing failures. Given the magnitude and clinical significance of this issue, the OIG would have expected leaders to evaluate the frequency and cause of the omission for all FITs and the impact on either specimen rejection rates or compromised test results due to processing specimens outside of the stability period.

Recommendations 1–5

1. The Facility Director reviews the more than 400 fecal immunochemical test specimens received by the laboratory to determine whether the processes completed were compliant with laboratory standards and policies, and ensures future specimens are received, accessioned, and processed by approved personnel.

2. The Veterans Integrated Service Network Director provides oversight of facility leaders' thorough review of laboratory fecal immunochemical test processing practices to ensure laboratory staff confirm that fecal immunochemical test specimens include the date the patient collected the specimen, utilize the collection date to determine stability, and accurately record and process specimens with strict adherence to specimen stability standards and Veterans Health Administration and facility policies, and monitors compliance.

3. The Facility Director establishes a multidisciplinary team (laboratory, primary care, gastroenterology, quality) to conduct a system-wide evaluation of the fecal immunochemical test

processes and practices across departments, identify areas for improvement (such as staff training, patient education, and standardized protocols), and implement recommended changes, and monitors for compliance and sustainment.

4. The Facility Director, in consultation with the Veterans Integrated Service Network's Chief of Pathology and Laboratory Medicine Service, modifies the facility's pre-printed fecal immunochemical test label to clearly identify a space and prompt for the patient to record the date the specimen was collected.

5. The Veterans Integrated Service Network Director, in consultation with the Pathology and Laboratory Medicine Service Program Office, Gastroenterology Program Office, and the Clinical Episode Review Team, evaluates the impact potential false-negative fecal immunochemical test results may have had on patients, and determines what measures need to be taken, including whether adverse event disclosures to patients are warranted.

Appendix A: FIT Processing

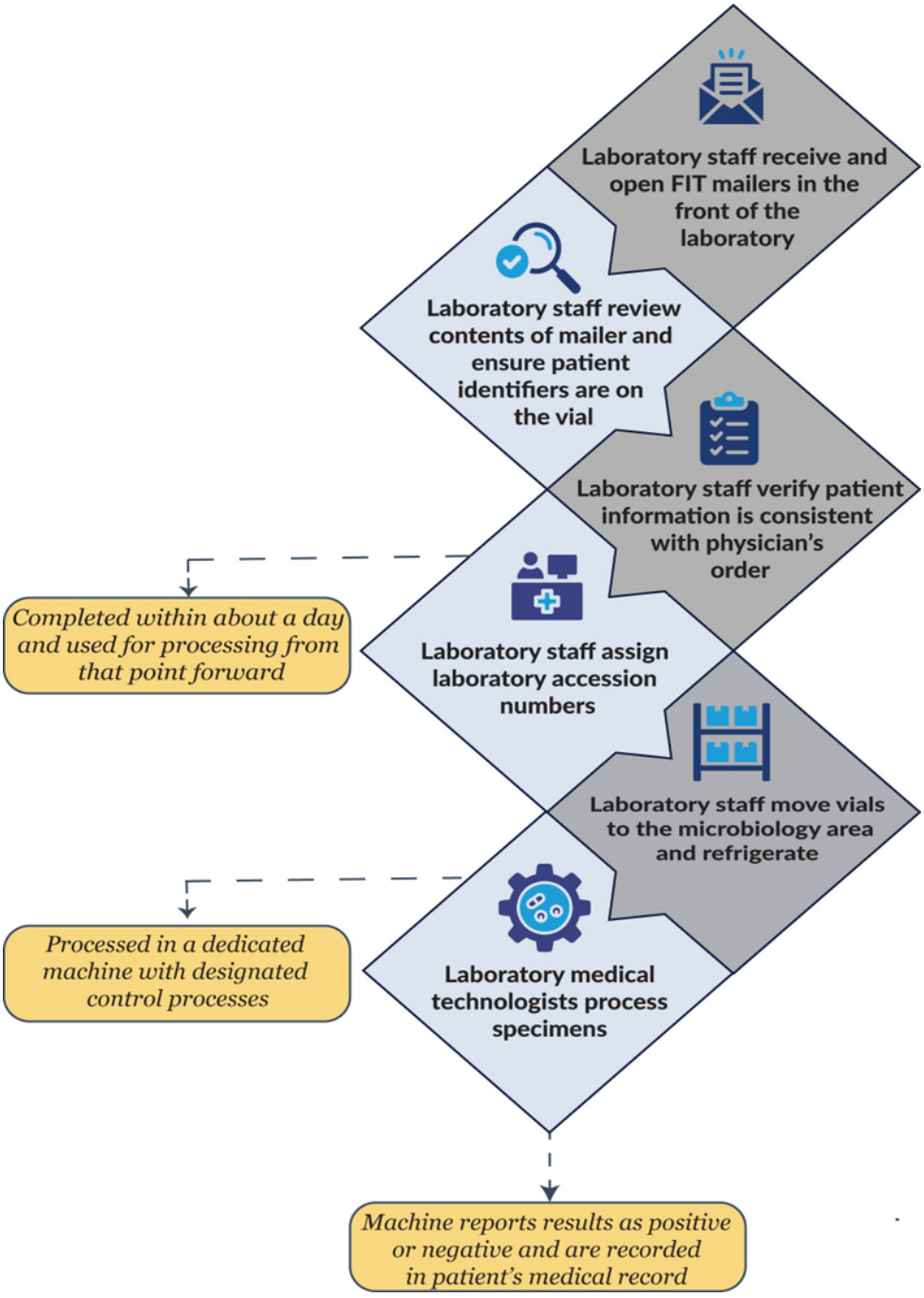

Figure A.1. *Fit Processing Steps.*
Source: Compiled from staff interviews, observations, and documents.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 4, 2023

From: Interim Network Director, VA Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection—Delayed Receipt of Patients' Colorectal Cancer Screening Tests at the Phoenix VA Health Care System in Arizona

To: Director, Office of Healthcare Inspections (54HL03)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) report, Delayed Receipt of Patients' Colorectal Cancer Screening Tests at the Phoenix VA Health Care System in Arizona.

2. Based on the thorough review of the report by VISN 22 Leadership, I concur with the recommendations and submitted action plans of Phoenix VA Health Care System and VISN 22.

3. If you have additional questions or need further information, please contact the VISN 22 Quality Management Officer.

(*Original signed by:*)

Bryan Arnette
VISN 22 Deputy Network Director

For

Steven E. Braverman, MD

VISN 22 Interim Network Director

VISN Director Response

Recommendation 2

The Veterans Integrated Service Network Director provides oversight of facility leaders' thorough review of laboratory fecal immunochemical test processing practices to ensure laboratory staff confirm that fecal immunochemical test specimens include the date the patient collected the specimen, utilize the collection date to determine stability, and accurately record and process specimens with strict adherence to specimen stability standards and Veterans Health Administration and facility policies, and monitors compliance.

_X _Concur

____Nonconcur

Target date for completion: September 30, 2023

Director Comments

On April 27, 2023, a safety standdown, led by the Veterans Integrated Service Network (VISN) and the Phoenix VA Health Care System (PVAHCS) Pathology and Laboratory Medicine Service (PLMS) leadership, occurred to retrain laboratory staff in fecal immunochemical test (FIT) specimen accessioning and processing. On April 27, 2023, the VISN 22 PLMS leadership reiterated to the seven other VISN 22 facilities' Clinical Laboratory Improvement Amendments'(CLIA) medical directors and lab managers, the requirement for collection dates to process FIT specimens.

Immediate actions taken as a part of the safety standdown: (1) paused FIT specimen accessioning, processing, and testing; (2) reviewed FIT specimen Standard Operating Procedure (SOP) to ensure consistency and compliance with the manufacturer's instruction for stability; (3)

lab staff re-educated on accessioning and processing FIT specimens with review of FIT SOP, accession criteria, and stability requisites; (4) reassessment and documentation of competency for lab staff responsible for accessioning and processing FIT specimens; (5) reiteration of the importance of adherence to sample stability requisites for accessioning, processing, and testing of FIT specimens.

On April 28, 2023, the lab staff responsible for accessioning and processing FIT specimens were reeducated, with documented competency assessment, and the accessioning, processing, and testing of FIT specimens resumed.

Beginning April 28, 2023, and ongoing, the Microbiology Supervisor performed weekly audits reviewing accessioned FIT specimens to assess if specimens contained collection dates or those that were out of stability were appropriately cancelled. Compliance has been at 100 percent for

the past four months. Of the 241 samples reviewed, during April 28, 2023 through August 29, 2023, 41 of 41 samples requiring cancellation were appropriately cancelled. This process will continue as a monthly Fiscal Year 2024 Key Performance Indicator for PVAHCS Pathology and Laboratory to ensure compliance to SOP (MIC 1013 OC-80 Auto Micro Fecal Immunochemical Test [FIT]).

Phoenix VA Health Care System and VISN 22 requests closure of this recommendation based on the evidence provided above.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 5

The Veterans Integrated Service Network Director, in consultation with the Pathology and Laboratory Medicine Service Program Office, Gastroenterology Program Office, and the Clinical Episode Review Team, evaluates the impact potential false-negative fecal immunochemical test results may have had on patients, and determines what measures need to be taken, including whether adverse event disclosures to patients are warranted.

_X _Concur

____Nonconcur

Target date for completion: October 2, 2023

Director Comments

On October 2, 2023, the Veterans Integrated Service Network (VISN) 22 and Phoenix VA Health Care System (PVAHCS) collaborated with the Clinical Episode Review Team (CERT) and in consultation with the Executive Director, National Pathology and Laboratory Medicine Service Program Office and National Director of Gastroenterology Program Office, determined that the clinical impact and risk of potential false negatives will have negligible impact on patients. In accordance with the VHA Directive 1004.08, the CERT team determined that potential false-negative fecal immunochemical test (FIT) cases do not warrant adverse event disclosures due to risk for harm being "minor" and having no implications for future care beyond the continued recommended screening.

Patients with inaccurate collection dates and potential false negative FIT test results from April 2022-April 2023 will be offered a new FIT kit for testing followed by recommended screenings. These FIT kits include revised patient instructions to reinforce capture of the collection date.

A memo from National Pathology and Laboratory Medicine and Gastroenterology Program Offices with updated guidance for processing FIT tests, without a collection date, is in the concurrence process.

Phoenix VA Health Care System requests closure of this recommendation based on the evidence provided above.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 2, 2023

From: Director, Phoenix VA Health Care System (644/00)

Subj: Healthcare Inspection—Delayed Receipt of Patients' Colorectal Cancer Screening Tests at the Phoenix VA Health Care System in Arizona

To: Interim Director, Desert Pacific Healthcare Network (10N22)

1. I have reviewed and concur with the OIG report, Healthcare Inspection—Delayed Receipt of Patients' Colorectal Cancer Screening Tests at the Phoenix VA Health Care System in Arizona.

2. I would like to thank the Office of Inspector General for their thorough review of this case and recommendations on process improvements. Phoenix VA Health Care System appreciates the opportunity to partner with the OIG on our high reliability journey. We remain steadfast in our commitment to zero harm.

3. If you have additional questions or need further information, please contact the Chief, Quality and Patient Safety.

(*Original signed by*:)

Bryan C. Matthews, MBA
Medical Center Director

Facility Director Response

Recommendation 1

The Facility Director reviews the more than 400 fecal immunochemical test specimens received by the laboratory to determine whether the processes completed were compliant with laboratory standards and policies, and ensures future specimens are received, accessioned, and processed by approved personnel.

_X _Concur

____Nonconcur

Target date for completion: July 30, 2023

Director Comments

The United States Postal Service (USPS) delivered 406 fecal immunochemical test (FIT) specimens to the Phoenix VA Health Care System (PVAHCS) mailroom on June 7, 2022. Upon mailroom delivery, the specimens were then taken to Pathology on the same date as delivery (June 7, 2022). In accordance with Lab Policies and Standard Operating Procedures each FIT specimen was assessed for acceptability by a certified Medical Technologist. Of the 406 FIT specimens, three (3) met appropriate labeling and stability criteria and were identified, accessioned, and processed for testing. The remaining 403 specimens did not meet criteria and were not processed secondary to labeling and stability issues.

Under normal circumstances, these tests would have been canceled by the Lab Medical Technologist in Veterans Health Information System Technology Architecture (VistA), due to being out of stability and an automated Computerized Patient Record System (CPRS) "cancellation notification" would be sent to the ordering provider. Given the large volume of delayed FIT kits received, a decision was made for the Patient-Aligned Care Team (PACT) coordinators to expedite the communication of the cancellation notification to each provider and ensure that additional testing was ordered for each patient.

The "FIT specimen" is unique in nature as it is the only PVACHS specimen/test that is patient-collected, patient-labeled, and delivered to Lab by the USPS. On April 28, 2023, Lab leadership began the staff re-inservice process with verification of competencies for handling, processing, and/or acceptance of FIT specimens with 100 percent (28/28) completion on May 24, 2023.

Phoenix VA Health Care System requests closure of this recommendation based on the evidence provided above.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 3

The Facility Director establishes a multidisciplinary team (laboratory, primary care, gastroenterology, quality) to conduct a system-wide evaluation of the fecal immunochemical test processes and practices across departments, identify areas for improvement (such as staff training, patient education, and standardized protocols), and implement recommended changes, and monitors for compliance and sustainment.

_X _Concur

____Nonconcur

Target date for completion: April 30, 2024

Director Comments

A Phoenix VA Health Care System (PVAHCS) multidisciplinary team, consisting of primary care nursing, quality, patient safety, laboratory, and supply chain staff, commenced in June 2022 and subsequently met four times from June 14, 2022 through July 18, 2022 to address the fecal immunochemical test (FIT) processes. A root cause analysis was initiated in June 2022 and action plans were closed in October 2022.

The bi-weekly Colorectal Cancer Screening workgroup began March 18, 2021 with the aim of improving metrics associated with colorectal cancer screening and included representatives from primary care, laboratory, quality, and Gastroenterology. The workgroup initiated and supported multiple performance improvement activities with a noted (eight percent) reduction of the performance gap since its inception. Current projects underway include: (1) the national gap reminder (timeframe from completed colonoscopy and identification of when next colonoscopy is due) closure with a target final completion date of Feb 28, 2024; (2) continuation of the "FIT kits mailed but not returned" initiative with use of Audiocare and postcards beginning September 2022, increasing our FIT return rate in the first six months by 11 percent; (3) October 2023 startup of the national Mailed FIT program with coordination of Supply Chain, Primary Care, Phoenix VA Laboratory, Fiscal, Clinical Applications and Informatics, Veterans Integrated Service Network (VISN) Lab and the offsite Government Print Office. The Colorectal Cancer Screening workgroup provided education and a platform for providers to opt-in, plus tracking to assure that as many teams as possible are enrolled. The purpose is to mail out FIT kits to average colorectal cancer risk Veterans who are due now, in the month of their birth.

On April 28, 2023, the PVAHCS Acting Chief of Lab, sent an email message to all medical and nursing staff outlining that the Lab would cancel all FIT test received without a collection date

from the patient. The email message also stated that the FIT test required two identifiers and must include the collection date to maintain stability (15 days at room temperature and 30 days refrigerated) and for medical and nursing staff to reorder and re-educate patients to add the mandatory date of collection which is needed for processing.

On May 1, 2023, the Interim Associate Chief of Staff of Primary Care Services sent an email message to the Patient-Aligned Care Team (PACT) providers, nursing staff, and Chief of Staff personnel advising that due to recent quality issues identified in the processing of FIT specimens, FIT kit ordering was suspended immediately. FIT kits already ordered would be reviewed and processed according to current lab standards but moving forward no more new FIT should be ordered at this time.

On May 1, 2023, the Chief of Gastroenterology notified PACT providers, nursing staff, and Chief of Staff personnel that the Gastrointestinal (GI) Clinic would be opened for screening colonoscopies to avoid delays in care for any Veteran who wants to complete colon cancer screening during this time.

A new patient education sheet was completed in July 2023 for aiding the Veteran in completing the requirements for FIT testing.

At the September 14, 2023 meeting for primary care staff, the new process for distributing FIT kits and educating Veterans on the improved process was presented and included: (1) the need for recording the date of use on the FIT kit, with specific locations on the kit for the Veteran to write the date; (2) staff were instructed to tell Veterans to complete the FIT kit and return to PVAHCS without delay. (3) additionally, May through September, FIT kits must be hand-delivered to the PVAHCS Lab locations to retain specimen integrity due to high Phoenix temperatures in this time period.

On September 18, 2023, the onsite facility FIT kit distribution was resumed with a new instruction sheet outlining the designated places to record the date of use. Reinforcement of the changes in process and availability of FIT kits had been promoted in nursing huddles and the Daily Management Systems Tier 3 huddles, leading up to September 18, 2023.

The Associate Chief of Staff of Primary Care Service, in collaboration with the Phoenix VA Laboratory, will monitor the collection label compliance. The number of labels with clear space for entry of collection date on FIT kits will be the numerator and the total number of FIT kits received will be the denominator. This information will be reported at the monthly Clinical Executive Board meetings for six consecutive months at 90 percent compliance.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 4

The Facility Director, in consultation with the Veterans Integrated Service Network's Chief of Pathology and Laboratory Medicine Service, modifies the facility's pre-printed fecal immunochemical test label to clearly identify a space and prompt for the patient to record the date the specimen was collected.

_X _Concur

____Nonconcur

Target date for completion: September 30, 2023

Director Comments

On May 25, 2023, the pre-printed fecal immunochemical test (FIT) ordering labels were revised to include the date of collection.

On August 10, 2023, the Veterans Integrated Service Network's (VISN) Chief of Pathology and Laboratory Medicine Service collaborated with the FIT test kit supplier (Polymedco, Inc.) to revise the FIT kit's patient sample collection instruction to include adding the collection date.

Phoenix VA Health Care System and VISN 22 requests closure of this recommendation based on the evidence provided above.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

OIG Contact and Staff Acknowledgments

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