

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1047526	(X3) Date Survey Completed 08/29/2023
Name of Provider or Supplier Project Of The Quad Cities, The	Street Address, City, State 4101 John Deere Road, Moline, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records, Certification and Survey Provider enhanced Reporting (CASPER) report 0096D, laboratory procedures, lack of documentation, and interview, the laboratory failed to: to make their results from the American Proficiency Institute (API) Gram Stain proficiency testing (PT) event one of 2021 publicly available (D2005), test microbiology Gram stain proficiency samples for the morphology component like patient specimens are tested and as instructed by the American Proficiency Institute (API) for eight of eight PT events reviewed from 2021 through 2023 (Refer to D2006), the laboratory received an unsatisfactory performance for American Proficiency Institute's (API) Gram Stain proficiency testing (PT) event one of two events reviewed in 2023 (Refer to D2020), and create and follow corrective actions for two of eight proficiency testing (PT) events for the American Proficiency Institute (API) Microbiology Gram Stain proficiency (Refer to 2026).</p>
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p>

Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute's (API) proficiency documents and Certification and Survey Provider enhanced Reporting (CASPER) report 0096D, the laboratory failed to make their results from the API Gram Stain proficiency testing (PT) event one of 2021 publicly available. Findings include: 1. Review of API Performance Summary 2021 Microbiology - 3rd Event confirmed no proficiency was graded for the first PT event of 2021. 2. Review of CASPER report 0096D showed that there is no documented result for this PT event.

D2006

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)

The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:
Based on review of procedures, proficiency testing (PT) records, and interviews, the laboratory failed to test microbiology Gram stain proficiency samples for the morphology component like patient specimens are tested and as instructed by the American Proficiency Institute (API) for eight of eight PT events reviewed from 2021 through 2023. Findings include: 1. Review of subsection VII Documentation in procedure, Gram Stain Procedure, stated: "i. Positive: One or more PMNs with intracellular gram-negative diplococci of typical morphology >2 wbc/GSPOS/obok. ii. Negative: No gram-negative intracellular diplococci present. Mononuclear cells and PMNs may or may not be present wbc Neg/GS Neg/obok." 2. Review of eight API PT records from February 2021 through 08/29/2023 showed that the morphological portion of the PT had not been performed for eight of eight events. 3. Review of API PT reporting instructions from the manufacturer stated: "3. For laboratories that perform Gram stains for GC screening only (i.e. Public Health Facilities) and do not test other sources, disregard the suggested specimen sources listed above. Use the reporting options listed below: - Gram Stain: Gram negative organism or No Gram negative organisms seen - Gram Stain Morphology: Diplococci or No diplococci seen" 4. Testing personnel #1 (TP1) confirmed the laboratory only performed the Gram stain portion and not the morphological portion of the PT event in an interview at 1:06pm on 08/29/2023. 5. Interview with TP1 at 1:53pm on 08/29 /2023 confirmed that morphology of bacteria are reviewed and documented for patient Gram stain testing.

D2020

BACTERIOLOGY
CFR(s): 493.823(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) documentation and Certification and Survey Provider enhanced Reporting (CASPER) report 0096D, the laboratory received an unsatisfactory performance for American Proficiency Institute's (API) Gram Stain proficiency testing (PT) event one of two events reviewed in 2023. Findings include: 1. Review of API PT records for two PT events in 2023 revealed that the laboratory received an unsatisfactory score of 60% for bacteriology in event one of 2023. 2. Review of CASPER report 0096D confirmed the laboratory received a 60% for the subspecialty of bacteriology for event one of 2023.

D2026

BACTERIOLOGY
CFR(s): 493.823(d)

(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records, interview, and lack of documentation the laboratory failed to create and follow corrective actions for two of eight proficiency testing (PT) events for the American Proficiency Institute (API) Microbiology Gram Stain proficiency. Findings include: 1. Review of eight API PT events from event one of 2021 through event two of 2023 showed that event one from 2021 and event one from 2023, received unknown and unsatisfactory scores, respectively (Refer to D2005 and D2020). 2. Review of API Performance Summary 2021 Microbiology - 1st Event revealed that it contained no results, was signed as being reviewed by the laboratory director (LD) on 05/28/2021, and no corrective action was taken in the Corrective Action Taken section. 3. Request to testing personnel number one (TP1) at 1:17pm on 08/29/2023 for documentation of corrective action for failure to submit PT event one of 2021 confirmed no corrective action documented. 4. Review of API Performance Summary 2023 Microbiology - 1st Event revealed an unsatisfactory score of 60 percent, was signed as being reviewed by the LD on 04/14/2023, and an unsatisfactory corrective action in the Corrective Action Taken section. a. The corrective action stated: "One slide was undecive and that why we cllid what we we called. One slide was entry error. We will we very carefull going forward entering data to the system. So we can avoid these error." 5. Review of the PT records failed to identify an entry error for event one of 2023 for Gram stain samples and the recorded results from the event were accurately transcribed and submitted to the PT provider.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general

laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on procedure review, document review, lack of documentation, and interview, the laboratory failed to: establish a written procedure for competency assessments for microbiology testing (D5209), assess ungraded proficiency testing samples for gram stain testing (D5215), and perform bi-annual method accuracy for vaginal wet mounts /potassium hydroxide preparations (D5219). , follow laboratory operating procedures (D5401), include test limitations in technical procedures (D5403), follow manufacturer's test instructions for Hardy GK400A stain kit (D5411, D5479), record every quality control test (D5479).

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview, the laboratory failed to establish written procedures to assess competency for vaginal wet mount/potassium hydroxide testing for mycology and parasitology and penile smear Gram stain testing for bacteriology. Findings include: 1. Review of the procedure manual found the laboratory lacked a competency procedure for assessing competency of testing personnel for vaginal wet mount/potassium hydroxide and penile smear Gram stain. 2. Interview with testing personnel #1 (TP1) on 08/29/2023 at 12:05pm confirmed the laboratory failed to have competency assessment procedure for the non-waived testing performed.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to verify the accuracy of non-graded analytes for bacteriology PT for one of eight events reviewed in 2021 through 2023. Findings include: 1. A review of laboratory documents found the laboratory lacked a policy and /or procedure for verifying the accuracy of analytes when they are ungraded due to non-consensus among participating laboratories. 2. A review of eight consecutive PT

	<p>events, from the 02/2020 through 08/29/2023, found that one of five PT samples from the first PT event of 2022 was ungraded by the PT provider and not verified for accuracy by the laboratory. a. PT sample - GS-05 - non-graded 3. Interview with testing personnel number one (TP1) at 1:16pm on 08/29/2023 confirmed that the ungraded sample for the first PT event of 2022 (GS-05) was not reviewed for accuracy by the laboratory.</p>
<p>D5219</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel number one (TP1), the laboratory failed to perform bi-annual method accuracy verification for wet mount/potassium hydroxide (KOH) testing of vaginal swabs from February 2021 through 08/29/2023. Findings include: 1. Review of laboratory records found the laboratory lacked documentation for bi-annual method accuracy for wet mount/KOH testing from February 2021 through 08/29/2023. 2. Interview with TP1 at 12:07pm on 08/29/2023 confirmed the laboratory failed to perform bi-annual method accuracy for wet mount/KOH testing.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, observation, manufacturer's package insert for Hardy GK400A Advanced Stain Kit, the laboratory's "Gram Stain Procedure" , patient test logs, patient test results, and interview the laboratory failed to: follow the procedures, "Laboratory Operating Standards" and "Gram Stain Procedure" for eight of eight patient records reviewed (D5401), the laboratory's Gram stain procedure failed to include the limitations of the test (D5403), perform Gram stain testing according to the manufacturer's instructions for Hardy Diagnostics catalog number GK400A, Advanced Gram Stain Kit (D5411), and follow manufacturer's specifications for using reagents from the Hardy GK400A Advanced Stain Kit and to document all control procedures performed for eight of eight patients reviewed (D5479).</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, observation, and interviews, the laboratory failed to follow the procedures, "Laboratory Operating Standards" and "Gram Stain Procedure" for eight of eight patient records reviewed. Findings include: 1. Records review, observation, and interviews showed the laboratory failed to follow the procedure, "Gram Stain Procedure", (Refer to 5479). 2. Review of the procedure, "Laboratory Operating Standards", revealed: "(1) Perform a gram stain control with each penile print viewed". 3. Review of patient records revealed that no quality control was documented for eight of eight penile print patients reviewed from 11/16 /2021 through 08/15/2023. a. Medical record numbers for the patients reviewed: 59769, 58982, 55246, 54481, 57118, 60541, 59760, and 58982. 4. Interview on 08/29 /2023 at 1:52 pm with testing personnel number one confirmed that the quality controls are not reviewed with each patient.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's package insert for Hardy GK400A Advanced Stain Kit and the laboratory's Gram stain procedure, "Gram Stain Procedure", the laboratory's Gram stain procedure failed to include the limitations of the test. Findings include: 1. Review of the manufacturer's package insert for the Hardy GK400A Advanced Stain Kit revealed five main limitations for testing: "a. Gram stain only provides preliminary identification information, and is not a substitute for culture. b. The Gram stain will not detect: organisms which exist within host cells, organisms with no cell wall, and organisms too small to be seen with light microscopy. Mycobacteria usually will not stain, and Legionella spp. stain only when taken directly from culture. Gram-negative bacteria that stain poorly with safranin include Campylobacter spp, Legionella spp., Bacteroides spp., Fusobacterium spp., and

Brucella spp. c. Certain conditions are known to damage the cell wall, causing gram-positive bacteria to falsely appear gram-negative or gram-variable. These include antibiotic treatment of the patient, cultures more than 48 hours old, inflammatory responses in the host, and autolytic enzymes. To minimize ambiguous results, specimens should be collected before the patient begins antibiotic therapy. Also, Gram stains should be performed on colonies taken from culture media that do not contain antibiotics, preferably on colonies that are 18-24 hours old. d. Precipitated crystal violet can occasionally appear as coccoid shapes or fungal elements, as well as other artifacts or background material, which may interfere with interpretation. e. Correct interpretation of Gram stains requires a theoretical background of bacteria and their morphology because improper technique or suboptimal reagents can cause unreliable results. Errors in technique which can alter Gram stain results include the following: i. Fixation with excessive heat alters cell morphology, makes organisms susceptible to over-decolorization, and can lead to the cells sloughing off the slide during the rinse steps. Always use methanol fixation. ii. Low concentrations of crystal violet make gram-positive organisms more susceptible to over-decolorization. iii. Insufficient exposure to iodine and lack of available fresh iodine can prevent crystal violet from bonding firmly with the cell wall, thus making gram-positive organisms more susceptible to over-decolorization. To ensure reliable Gram stain results, only fresh iodine should be used. iv. Prolonged decolorization, especially with acetone, can cause gram-positive bacteria to appear gram-negative. Insufficient decolorization can make gram-negative organisms falsely appear gram-positive. v. Insufficient counterstaining can fail to stain gram-negative bacteria and background material, whereas excessive counterstaining will leach the crystal violet-iodine complex from gram-positive bacteria and stain them with safranin, thus making them falsely appear gram-negative. vi. Prolonged washing between any of the steps can cause over-decolorization." 2. Review of the laboratory's gram stain procedure, "Gram Stain Procedure", found the procedure failed to reference the limitations outlined in the Hardy GK400A Advanced Stain Kit.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on direct observation, review of the manufacturer's package insert for the Hardy GK400A Advanced Gram Stain Kit, the laboratory's "Gram stain procedure", test volume records, and interview, the laboratory failed to perform Gram stain testing according to the manufacturer's instructions for Hardy Diagnostics catalog number GK400A, Advanced Gram Stain Kit. Findings: 1. Observations on initial tour of the laboratory at 11:00am on 08/29/2023 with testing personnel one (TP1) showed: use of the Hardy GK400A Advanced Gram Stain Kit, a slide warmer, the absence of methanol reagent, and that Gram stains were timed to 21 seconds per stain and mordant. 2. Review of the Hardy GK400A Advanced Gram Stain Kit with the manufacturer's test system package insert and the laboratory's "Gram Stain procedure" found they both indicated slides should be air dried, fixed with methanol, and the stains and mordant should be done for 60 seconds. 3. An additional observation and interview was conducted to verify the gram staining procedure at 1:48pm with TP1

and confirmed the following: a. TP1 used heat to dry slides, contrary to the manufacturer's directions and laboratory procedure. b. TP1 failed to fix slides with methanol, contrary to the manufacturer's directions and laboratory procedure. c. TP1 used staining and mordant times of 21 seconds, contrary to the manufacturer's directions and laboratory procedure. 4. Test volume records indicated the laboratory performed 780 grams stains from July of 2022 through July of 2023. 5. Interview with TP1 at 4:09 pm on 8-29-2023 confirmed the laboratory failed to follow the Hardy GK400A Advanced Gram Stain Kit with the manufacturer's test system package insert and the laboratory's "Gram stain procedure".

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's "Gram Stain Procedure", the package insert for the Hardy GK400A Advanced Stain Kit, patient test logs, patient test results, and interview, the laboratory failed to follow manufacturer's specifications for using reagents from the Hardy GK400A Advanced Stain Kit and to document all control procedures performed for eight of eight patients reviewed. Findings include: 1. Review of procedure, "Gram Stain Procedure", showed: "a. Each gram stain slide contains a set of controls and a designated area to place the urethral smear. On board controls will be completed by the technician reading the slide. b. Record the obok (On Board controls are O.K.) in the laboratory logbook to reflect the positive/negative organisms seen on the slide." 2. Review of patient test logs from 01/2021 through 08/2023 showed that "obok" is not recorded with each slide. 3. Review of patient records revealed the laboratory failed to document quality controls for Gram stain testing for eight of eight patients reviewed from 11/16/2021 through 08/15/2023 (Refer to D5401). 4. The laboratory failed to perform Gram stain testing according to the manufacturer's instructions for Hardy Diagnostics catalog number GK400A, Advanced Gram Stain Kit in use (Refer to 5411). 5. Interview on 08/29/2023 at 4:09pm with testing TP1 confirmed the laboratory failed to follow the manufacturer's instructions and document quality control results for Gram stain testing.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review, proficiency testing records, the laboratory's "Gram Stain Procedure", "Laboratory Operating Standards" procedure, patient test reports, patient testing logs, lack of documentation, observations, and interviews, the laboratory director failed to: ensure four of four testing personnel are performing the Gram stain testing as required by laboratory procedure, "Gram Stain Procedure" (D6014), ensure

that Gram stain proficiency testing samples were tested in the same manner as patient samples, to include morphology for eight of eight PT events reviewed (D6016), ensure the Quality Assurance portion of the "Laboratory Operating Standards" procedure was maintained as no "STD/HIV chart audits" where performed every three months in 2021 through 8-29-2023 (D6021), ensure that the Gram stain test reports included the pertinent information, as outlined in the "Gram Stain Procedure", to interpret the results for eight of eight patient test reports reviewed (D6026), ensure one of four testing personnel, testing personnel number four (TP4), had the required training prior to performing Gram stain testing (D6029), and establish written procedures to assess competency for vaginal wet mount/potassium hydroxide testing for mycology and parasitology and penile smear Gram stain testing for bacteriology (D6030).

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on records review, observation, and interviews, the laboratory director failed to ensure that four of four testing personnel are performing the Gram stain testing as required by laboratory procedure, "Gram Stain Procedure", (Refer to D5401, 5411, 5479).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the "Gram Stain Procedure", proficiency testing records, and interview, the laboratory director failed to ensure that Gram stain proficiency testing samples were tested in the same manner as patient samples, to include morphology for eight of eight PT events reviewed (Refer to D2006).

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the "Laboratory Operating Standards" procedure, lack of documentation, and interview, the laboratory director failed to ensure the Quality Assurance portion of the "Laboratory Operating Standards" procedure was maintained as no "STD/HIV chart audits" were performed every three months in 2021 through 8-29-2023. Findings: 1. Review of the Quality Assurance section of the procedure, "Laboratory Operating Standards", revealed: "(2) For quality assurance, an STD/HIV chart audit is performed every three months". 2. Review of laboratory quality assurance records found no three-month chart audit reviews were documented in 2021 through the date of survey (8-29-2023). 3. Interview with testing personnel number one (TP1) at 3:26pm on 08/29/2023 confirmed the laboratory failed to document chart audits every three months as outlined in the "Laboratory Operating Standards" procedure.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's "Gram Stain Procedure", patient test reports, and interview the laboratory director failed to ensure that the Gram stain test reports included the pertinent information, as outlined in the "Gram Stain Procedure", to interpret the results for eight of eight patient test reports reviewed. Findings: 1. Review of procedure, "Gram Stain Procedure", showed that a Gram stain can be resulted three ways: a. Positive for Gonorrhea: one or more PMNs with intracellular gram-negative diplococci of typical morphology > 2wbc/GSPOS/obok. b. Negative for Gonorrhea: no gram-negative intracellular diplococci present. Mononuclear cells and PMNs may or may not be present wbc Neg/GS Neg/obok. c. Nongonococcal Urethritis (NGU): greater than or equal to two PMNs per immersion oil field and no gram-negative intracellular or gram positive diplococci are present >2wbc/GSNEG /obok. 2. Review of eight of eight Gram stain patient test reports found they were resulted as either "pos" or "neg" for Gram stain. a. Test reports for medical record numbers (MRNs) 57118 and 58982 stated Gram Stain final result is "pos". b. Test reports for MRNs 54481, 59769, 58982, 55246, 60541, and 59760 stated Gram Stain final result is "neg". 3. Interview with testing personnel number one (TP1) at 4:09pm on 08/29/2023 confirmed that Gram stain test reports failed to follow the "Gram Stain Procedure" for resulting.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on lack of documentation, patient testing logs, and interview, the laboratory director failed to ensure one of four testing personnel, testing personnel number four (TP4), had the required training prior to performing Gram stain testing. Findings: 1. Review of training records revealed no training documentation for TP4. 2. Review of patient testing logs from 06/30/2023 through 08/29/2023 showed TP4 performing Gram stain testing independently. 3. Interview with testing personnel number one (TP1) at 4:09pm on 08/29/2023 confirmed the lack of training documentation for TP4.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview, the laboratory director failed to establish written procedures to assess competency for vaginal wet mount/potassium hydroxide testing for mycology and parasitology and penile smear Gram stain testing for bacteriology (Refer to D5209, D6046).

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the Laboratory Personnel Report (CMS-209), competency assessment records, and interview with testing personnel number one (TP1), the

technical consultant failed to evaluate the competency of three of four testing personnel for vaginal wet mount/potassium hydroxide preparations and Gram stain testing from 2021 through 08/29/2023 (Refer to 6046).

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Personnel Report (CMS-209), competency assessment records, and interview with testing personnel number one (TP1), the technical consultant failed to evaluate the competency of three of four testing personnel for vaginal wet mount/potassium hydroxide preparations and Gram stain testing from 2021 through 08/29/2023. Findings: 1. Review of the CMS-209 Laboratory Personnel Report showed that the laboratory director is also the technical consultant (TC) and the laboratory had four testing personnel (TP1, TP2, TP3, and TP4). 2. Review of competency assessment records for Gram stains and vaginal wet mount/potassium hydroxide preparation found "Personnel Competency Assessment" forms for TP1, TP2, and TP3 were performed by another testing personnel and not the TC for all assessments reviewed in 2021 through 8-29-2023. 3. Interview with TP1 at 12:02pm on 08/29/2023 confirmed that the testing personnel assess each other's competency for non-waived testing.