Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0488544	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Heart Of Texas Community Health Center Inc	1600 Providence Drive, Waco, TX	

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
D0000	Based on an announced validation survey, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D5006 - 42 C.F.R. 493.1203 Condition: Mycology; D5012 - 42 C.F.R. 493.1207 Condition: Syphilis serology; D6033 - 42 C. F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on review of the pre-survey paperwork, proficiency testing (PT) records, and interview, the laboratory failed to enroll in proficiency testing for the subspecialty of mycology for the presence or absence of fungi for Dermatophytes for 24 of 24 months reviewed in 2023 and 2024. Findings follow. A. Review of the pre-survey paperwork showed the laboratory tested for Dermatophytes. B. Review of the College of American Pathologists (CAP) PT records for 2024 showed the laboratory was not enrolled in PT for the presence or absence of a Dermatophyte. C. Interview with the

	Director of Laboratory Services on April 8, 2025 at 1545 hours in the conference room confirmed they were not enrolled. D. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 142.
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory policy and procedure, temperature charts, laboratory records, interview and pre-survey paperwork, the laboratory failed to meet the requirements for the Specialty when they failed to follow manufacturer instructions of incubating the Remel Dermatophyte Test Medium (DTM) at 25 - 30 Celsius (C) for 276 of 295 days reviewed (refer to D5411).
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, laboratory policies and procedures, function check records, interview, observation, testing logs, and presurvey paperwork, the laboratory failed to meet the requirements for the Specialty when they failed to follow the manufacturer's instructions for verifying the dispense volume of the needle and the rotator speed when testing 53 of 53 patient samples for the RPR (Rapid Plasma Reagin) card test on April 9, 2025 (refer to D5431 I and II).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 review of the manufacturer's instructions, the laboratory policy and procedure, temperature charts, laboratory records, interview and pre-survey paperwork, the laboratory failed to follow manufacturer instructions of incubating the Remel Dermatophyte Test Medium (DTM) at 25 - 30 Celsius (C) for 276 of 295 days reviewed. Findings follow. A. Review of the DTM package insert, 10/05/2010, under Procedure stated, "4. Incubate in ambient air at 25 - 30 C for up to 14 days." B. Review of the laboratory's policy and procedure titled Procedure Fungal Culture, revised 01/11/2006, under Procedure stated, "1. Slants should come to the laboratory

	already inoculated. If not, inoculate the slants with as much specimen as possible. 2. Screw the cap of the culture bottle on loosely. Screwing the top on tightly may prevent fungus from growing. 3. Place the bottle on an open counter or shelf. 4. At 7 days the culture should be read and again at 14 days. Any growth after this time is not considered to be positive for a pathogenic fungus..." The incubation temperature was not included in the laboratory policy and procedure. C. During a tour of the laboratory on April 9, 2025 at 1620 hours surveyor observed two DTM specimens incubating in a rack on top of the microbiology incubator: 1. MRN 5364601 2. MRN 23090995. D. Review of the Daily Temperature/Humidity Record from January 2024 - December 2024 showed the acceptable daily temperature (temp) was 22 - 26 C and the laboratory was cooler than 25 C on 276 days as listed by months of testing: Days temp documented/Month/ Temperatures/ Days documented out of range 1. - 24. / January 2024/ 22 - 23 C/ 24 of 24 25. - 49./ February 2024/ 22 - 23.8 C/ 25 of 25 50. - 75./ March 2024/ 21 - 23 C/ 26 of 26 76. - 101./ April 2024/ 22 - 24 C/ 26 of 26 102. - 125. / May 2024/ 22 - 23 C/ 24 of 24 126. - 149./ June 2024/ 22 - 23 C/ 24 of 24 150. - 172. / July 2024/ 22 - 24 C/ 23 of 23 173. - 199./ August 2024/ 22 - 23 C/ 27 of 27 200. - 220./ September 2024/ 22 - 26 C/ 21 of 23 221. - 245./ October 2024/ 23 - 26 C/ 25 of 27 246. - 266./ November 2024/ 23 - 25 C/ 21 of 22 267. - 276./ December 2024/ 22 - 27 C/ 10 of 24 E. Interview with the Director of Laboratory Services on April 8, 2025 at 1520 hours in the office confirmed the findings. F. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 142.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, stability study, patient reports, presurvey paperwork, and interview, the laboratory failed to ensure an extended specimen stability study was performed for the Complete Blood Count (CBC) on the Sysmex XN-450 for four out of five patient samples reviewed. Findings follow. A. Review of the Sysmex XN-450 Basic Operation manual, 06/2017, at 4.3 Preparing Samples, for Handling Whole Blood stated, "The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8 degrees Celsius until it can be analyzed..." The manufacturer did not define the stability of the CBC beyond 4 hours after collection. B. Review of the Sysmex XN-450 General Information manual, at Chapter 5 Instrument Specifications stated, "Long term stability is determined by comparing the results of the initial analysis (within 2 hours of collection) to results from samples stored at controlled room and refrigerated temperature for 48 hours..." C. Review of the laboratory's policy and procedure titled

	Sysmex XN-550, effective 04/22/2019, under Specimen stated, "E. Stored Specimen Stability 1. EDTA blood sample should be analyzed within 4 hours. 2. If samples cannot be analyzed within 4 hours, store in a refrigerator at 2 to 8 C..." The procedure did not define the stability of the CBC beyond 4 hours after collection. D. The laboratory's specimen stability study was requested on April 9, 2025 at 1700 hours but not provided. E. Review of patient reports on a randomly selected date from the outpatient clinics "packing slips" revealed they exceeded the manufacturer's stability of 4 hours as listed by Sample ID, date and time of collection, date and time released, and elapsed time: Sample ID Test Collection date and time Released date and time Elapsed Time 1. 24113090080 CBC 11/04/2024 @ 8:16 am 11/04/2024 @ 12:19 pm 4 hours 3 minutes 2. 24113090529 CBC 11/04/2024 @ 9:27 am 11/04/2024 @ 3:12 pm 5 hours 45 minutes 3. 24113090633 CBC 11/04/2024 @ 10:27 am 11/04/2024 @ 4:49 pm 6 hours 22 minutes 4. 24113090820 CBC 11/04/2024 @ 11:08 am 11/04 /2024 @ 4:49 pm 5 hours 41 minutes F. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 126,690. G. Interview with the Director of Laboratory Services on April 9, 2025 at 1700 hours in the office confirmed a stability study to establish the extended specimen stability of the CBC was not performed.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: I. Based on manufacturer's instructions, laboratory policies and procedures, function check records, interview, observation, testing logs, and presurvey paperwork, the laboratory failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the carbon antigen when testing 53 of 53 patient samples for the RPR (Rapid Plasma Reagin) card test on April 9, 2025. Findings follow. A. Review of the package insert for the BD Macro-Vue RPR Card Tests for Syphilis, 2021, under Procedures and Results at Preliminary Preparations stated, "Check delivery of the needle by placing the needle firmly on a 1 mL pipet or syringe; fill the pipet or syringe with antigen suspension, and holding the pipet or syringe in a vertical position, count the number of drops delivered in 0.5 mL. The correct number of drops is given in the table opposite: Color of needle hub = yellow, 20 Guage, Number of drops in 0.5 mL = 30 +/-1 drop." B. Review of the laboratory policy and procedure titled Procedure- Macro-Vue RPR Card Test, revised 01/05 /2006, under Calibration stated "Dispensing Needle The dispensing needle for the antigen may be checked by the following method: Attach the hub end of the needle to the tip of a 1 mL pipette or syringe. Fill the pipette or syringe with antigen suspension, and holding the pipette or syringe in a vertical position, count the number of drops delivered in a 0.5 mL. There should be 30 +/- 1 drops per 0.5 mL. Record results on the daily worksheet." C. Review of the RPR QC Log from 01/09/2024 - 12 /27/2024 showed the needle drop check was recorded as 30 every day of patient testing reviewed. D. Interview on April 9, 2025 at 1425 hours in the laboratory with testing personnel #2 (TP#2) (as listed on the CMS Form 209) at the RPR bench

surveyor requested demonstration of the needle drop check but TP#2 did not know how to do it. When asked where they got the number 30 to record on the log, she stated the needle they used was calibrated to dispense 30 drops and that is what they write on the log. Interview on April 9, 2025 at 1430 hours with TP #4 stated they used pre-calibrated needles that dispensed 30 drops and write that number on the log. Interview with the general supervisor/testing personnel #1 on April 9, 2025 at 1435 hours could not recall if she had ever performed a needle drop check and would look up the procedure for a demonstration. E. Demonstration of the RPR antigen needle drop check by the general supervisor/TP #1 conducted April 9, 2025 at 1440 hours in the laboratory dispensed 36 drops of 0.5 mL carbon antigen: the needle drop check failed. F. Review of the RPR working log showed 53 patients were performed on April 9, 2025 as listed by Sample ID: 1. 2504094189 2. 25040941663 3. 25040970030 4. 25040970214 5. 25040970407 6. 25040970663 7. 25040970690 8. 25040970733 9. 25040970773 10. 25040971019 11. 25040971042 12. 25040971235 13. 25040971288 14. 25040971501 15. 25040971545 16. 25040971664 17. 25040971691 18. 25040971718 19. 25040971748 20. 25040980172 21. 25040980203 22. 25040980215 23. 25040980259 24. 25040980339 25. 25040980400 26. 25040980417 27. 25040980440 28. 25040980522 29. 25040980539 30. 25040980596 31. 25040980608 32. 25040980646 33. 25040980716 34. 25040980783 35. 25040980825 36. 25040980905 37. 25040980938 38. 25040980967 39. 25040981003 40. 25040981036 41. 25040981088 42. 25040981181 43. 25040981207 44. 25040981233 45. 25040981280 46. 25040981290 47. 25040981368 48. 25040981416 49. 25040981431 50. 25040981435 51. 25040981477 52. 25040981516 53. 25040981767 G. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 6,130. II. Based on manufacturer's instructions, laboratory policies and procedures, function check records, interview, observation, testing logs, and presurvey paperwork, the laboratory failed to follow the manufacturer's instructions for verifying the rotator speed when testing 53 of 53 patient samples for the RPR (Rapid Plasma Reagin) card test on April 9, 2025. Findings follow. A. Review of the package insert for the BD Macro-Vue RPR Card Tests for Syphilis, 2021, under Procedures and Results at Materials Required but not Provided stated, "2. A rotator, 100 +/- 2 rpm, circumscribing a circle 2 cm in diameter, with automatic timer, friction drive, and a cover containing a moistened sponge or blotter." And under Procedures and Results at 18mm Qualitative Card Test Using BD Dispenstirs Devices: "5. Rotate for 8 min (+/- 30 s) under humidifying cover, on mechanical rotator at 100 +/- 2 rpm." B. Review of the laboratory policy and procedure titled Procedure- Macro-Vue RPR Card Test, revised 01/05/2006, under Calibration stated "100 rpm Rotator The rotator must be calibrated to 95 - 110 rpm. The optimal speed is 100 +/- 2 rpm. To check rotation speed, turn on the rotator and holding your thumb against the edge of the rotator plate, count the number of times it hits your thumb in one minute. Record rpm on the daily worksheet. This must be done on each day of use." And under Test Procedure stated, "9. Rotate for 8 minutes (+/- 30 sec), under humidifying cover with moistened sponge, on mechanical rotator at 100 +/- 2 rpm." The manufacturer required a rotator speed of 98 - 102. C. Review of the RPR QC Log from 01/09/2024 - 12/27/2024 showed the rotator speed check was recorded as 100 every day of patient testing reviewed. D. Interview on April 9, 2025 at 1425 hours in the laboratory with testing personnel #2 (TP#2) when asked where they got the number 100 to record on the log, she stated they set the rotator speed to 100 on the dial and record that on the log. Interview on April 9, 2025 at 1430 hours with TP #4 stated they get the 100 from the setting they use on the rotator. Interview with the general supervisor/testing personnel #1 on April 9, 2025 at 1450 hours confirmed she had not performed a rotator speed check before. E. Demonstration of the rotator speed check by the general supervisor/TP #1 conducted

	April 9, 2025 at 1445 hours in the laboratory obtained 110 rotations in a minute: the rotator speed check failed. F. Review of the RPR working log showed 53 patients were performed on April 9, 2025 as listed by Sample ID: 1. 2504094189 2. 25040941663 3. 25040970030 4. 25040970214 5. 25040970407 6. 25040970663 7. 25040970690 8. 25040970733 9. 25040970773 10. 25040971019 11. 25040971042 12. 25040971235 13. 25040971288 14. 25040971501 15. 25040971545 16. 25040971664 17. 25040971691 18. 25040971718 19. 25040971748 20. 25040980172 21. 25040980203 22. 25040980215 23. 25040980259 24. 25040980339 25. 25040980400 26. 25040980417 27. 25040980440 28. 25040980522 29. 25040980539 30. 25040980596 31. 25040980608 32. 25040980646 33. 25040980716 34. 25040980783 35. 25040980825 36. 25040980905 37. 25040980938 38. 25040980967 39. 25040981003 40. 25040981036 41. 25040981088 42. 25040981181 43. 25040981207 44. 25040981233 45. 25040981280 46. 25040981290 47. 25040981368 48. 25040981416 49. 25040981431 50. 25040981435 51. 25040981477 52. 25040981516 53. 25040981767 G. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 6,130.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: I. Based on review of the calibration verifications, calibrations, interview, and pre-survey paperwork, the laboratory failed to perform calibration verification every six months for Vitamin B12 performed on the Ortho Clinical Diagnostics Vitros XT 7600 for four of four events reviewed in 2023 and 2024. Findings follow. A. Review of the calibration verification records showed none for Vitamin B12. Review of the calibrations showed 2 calibrators. Calibration verifications were requested on April 8, 2025 at 1115 hours but not provided. B. Interview with the Director of Laboratory Services on April 8, 2025 at 1115 hours in the conference room confirmed they did not perform calibration verifications on Vitamin B12 [in 2023 and 2024]. C. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 2,877. II. Based on review of the calibration verification, interview, and pre-survey paperwork, the laboratory failed to perform calibration verifications every six months for Hemoglobin A1C (Hgb A1C) performed on the Tosoh G8 for two out of three events over 18 months reviewed. Findings follow. A.

	Review of the calibration verifications performed for Hgb A1C on the Tosoh G8 showed calibration verifications were performed: 1. 08/17/2023, 2. 03/19/2024 (elapsed time 7 months) 3. 1/31/2025 (elapsed time 10 months). Review of the calibrations showed 2 calibrators. Additional calibration verifications were requested but not provided. B. Interview with the Director of Laboratory Services on April 8, 2025 at 1115 hours in the conference room confirmed the findings. C. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 34,315. III. Based on review of the calibration verification, interview, and pre-survey paperwork, the laboratory failed to perform calibration verifications every six months for Total Iron Binding Capacity (TIBC) performed on the Ortho Clinical Diagnostics Vitros XT 7600 for one out of four events over 20 months reviewed. Findings follow. A. Review of the calibration verifications performed for TIBC showed calibration verifications were performed: 1. 05/11/2023, 2. 04/12/2024 (elapsed time 11 months) 3. 07/02/2024, 4. 01/10/2025. Review of the calibrations showed 2 calibrators. Additional calibration verifications were requested but not provided. B. Interview with the Director of Laboratory Services on April 8, 2025 at 1115 hours in the conference room confirmed the findings. C. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 1,069. IV. Based on review of the calibration verification, interview, and pre-survey paperwork, the laboratory failed to perform calibration verifications every six months for Vitamin D performed on the Ortho Clinical Diagnostics Vitros XT 7600 for one out of four events over 19 months reviewed. Findings follow. A. Review of the calibration verifications performed for Vitamin D showed calibration verifications were performed: 1. 06/07/2023, 2. 04/12/2024 (elapsed time 10 months) 3. 07/03/2024, 4. 01/23/2025. Review of the calibrations showed 2 calibrators. Additional calibration verifications were requested but not provided. B. Interview with the Director of Laboratory Services on April 8, 2025 at 1115 hours in the conference room confirmed the findings. C. Review of the pre-survey paperwork annual test volume calculations worksheet showed an annual test volume of 4,213.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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 manufacturer's instructions, laboratory policies and procedures, function check records, interview, observation, testing logs, and presurvey paperwork, the laboratory director failed to ensure testing personnel followed manufacturer's instructions for verifying the dispense volume of the needle and the rotator speed when testing 53 of 53 patient samples for the RPR (Rapid Plasma Reagin) card test on April 9, 2025 (see D5431 I and II).
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 proficiency testing (PT) records, manufacturer's instructions, laboratory policies and procedures, function check records, interview, observation, testing logs, competency evaluations, and presurvey paperwork, the Technical Consultant failed to provide the required technical oversight of the laboratory for two of two years reviewed. Findings follow. 1. The technical consultant failed to enroll in proficiency testing for the detection of Dermatophytes for 24 of 24 months reviewed in 2023 and 2024 (see D6041). 2. The technical consultant failed to identify training needs when testing personnel failed to follow the manufacturer's instructions for verifying the dispense volume of the needle and the rotator speed when testing 53 of 53 patient samples for the RPR (Rapid Plasma Reagin) card test on April 9, 2025 (see D6045). 3. The technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for six out of 10 testing personnel competencies reviewed for moderately complex testing in 2023 and 2024 (see D6051). 4. The technical consultant failed to evaluate and document the performance of individuals responsible for performing moderate complexity testing at least semiannually during the first year the individual tests patient specimens for one of one new employees reviewed (see D6053).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the pre-survey paperwork, proficiency testing (PT) records, interview, and internet search, the technical consultant failed to enroll in proficiency testing for the detection of Dermatophytes for 24 of 24 months reviewed in 2023 and 2024 (see D2000).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on manufacturer's instructions, laboratory policies and procedures, function check records, interview, observation, testing logs, and presurvey paperwork, the technical consultant failed to identify training needs when testing personnel failed to follow the manufacturer's instructions for verifying the dispense volume of the needle and the rotator speed when testing 53 of 53 patient samples for the RPR (Rapid Plasma Reagin) card test on April 9, 2025 (see D5431 I and II).
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, and interview, the technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for six out of 10 testing personnel competencies reviewed for moderately complex testing in 2023 and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Employee Orientation and Competency Assessment, effective 01/08/2018, under Competency Assessment stated, "Each employee will have competency assessed and documented for each procedure the employee performs. This is done at initial training, six months after initial employment and annually therafter... Competency is assessed using a combination of the following methods: ...e. Assessment of test performance through testing previously analyzed specimens, internal blind samples or external proficiency testing samples..." B. Review of the competency evaluations showed the following testing personnel were missing test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: 1. Testing personnel #1 (TP#1) (as listed on the CMS Form 209) from 2023 was missing chemistry, endocrinology, immunology, and toxicology testing on the Vitros 5600, Hemoglobin A1C (HgbA1C) on the Tosoh G8, Chlamydia, Neisseria gonorrhoeae and group B Streptococcus (group B Strep) on the GenExpert; 2. TP#2 from late 2024 was missing the Complete Blood Count (CBC) on the Sysmex XN500, colony count urine cultures; 3. TP#3 from 2023 was missing CBC on the Sysmex XN500, microscopic and chemical urinalysis, colony count urine cultures, HgbA1C on the Tosoh G8, Chlamydia, Neisseria gonorrhoeae and group B Strep on the GenExpert, Rapid Plasma Reagin (RPR), serum pregnancy test 4. TP#3 from 2024 was missing microscopic and chemical urinalysis, colony count urine cultures, RPR, serum pregnancy test; 5. TP#7 from 2023 was missing microscopic and chemical urinalysis, colony count urine cultures, HgbA1C on the Tosoh G8, Chlamydia, Neisseria gonorrhoeae and group B Strep on the GenExpert; 6. TP#7 from 2024 was missing microscopic and chemical urinalysis, colony count urine cultures C. Interview with the Director of Laboratory Services on April 8, 2025 at 1015 hours in the conference room confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, competency evaluations, and interview, the technical consultant failed to evaluate and document the performance of individuals responsible for performing moderate complexity testing at least semiannually during the first year the individual tests patient specimens for one of one new employees reviewed. Findings follow. A. Review of the pre-survey paperwork titled Laboratory Personnel, and training and competency evaluation records showed testing personnel #2 (as listed on the CMS Form 209) was hired 05/22/2023. Documentation of training was performed 05/25/2023 - 08/17/2023 and a six-month competency evaluation was performed late 2024. An additional competency evaluation was requested on April 8,

	2025 at 1145 hours but not provided. B. Interview with the Director of Laboratory Services on April 8, 2025 at 1145 hours in the conference room confirmed the findings.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, and interview, the technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for three out of 10 testing personnel competencies reviewed for high complexity testing in 2023 and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Employee Orientation and Competency Assessment, effective 01/08/2018, under Competency Assessment stated, "Each employee will have competency assessed and documented for each procedure the employee performs. This is done at initial training, six months after initial employment and annually therafter... Competency is assessed using a combination of the following methods: ...e. Assessment of test performance through testing previously analyzed specimens, internal blind samples or external proficiency testing samples..." B. Review of the competency evaluations showed the following testing personnel were missing test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: 1. Testing personnel #1 (TP#1) (as listed on the CMS Form 209) from 2023 was missing the high complexity chemistry, endocrinology, immunology testing on the Vitros 5600 2. TP#2 from late 2024 was missing manual differentials 3. TP#3 from 2023 was missing manual differentials. C. Interview with the Director of Laboratory Services on April 8, 2025 at 1015 hours in the conference room confirmed the findings.