Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0628373	12/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Harney District Hospital Lab	557 W Washington St, Burns, OR	

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
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) (a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) for Blood Bank (BB) in 2024, it was revealed that the laboratory failed to attain a total score of 100% for Compatibility Testing for BB event #3. Interview with the Technical Supervisor (TS) confirmed the unsatisfactory score for API BB event #3 Compatibility testing. Findings include: 1. Upon review of the scores for the specialty BB, the laboratory failed to attain a score of 100% for Compatibility testing for event #3 in 2024. 2. Upon request for written documentation of a complete corrective action (CA) or TS follow up for Compatibility Testing event #3, none could be produced. 3. Interview with the Technical Supervisor (TS #2) on 12/10/2025 at 10:30 am confirmed that there was no CA for BB testing event #3 in 2024. 4. The laboratory reports performing 667 BB related assays annually.
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 laboratory personnel records and interview with the Technical Supervisor (TS #2), the laboratory failed to ensure that the persons delegated by the Laboratory

	Director (LD) to a federal position, inluding Technical Consultant (TC), Technical Supervisor (TS), and General Supervisor (GS) listed on the current CMS 209 form, were assessed at least annually, based on a written policy and procedure. Findings include: 1. Upon request for the laboratory's policy on assessment of laboratory personnel that hold the title of TC, TS,and GS, none could be produced. 2. Upon request for competency assessments by the Laboratory Director (LD) for personnel listed as the TC, TS and GS on the current CMS 209 form 12/09/2025 and the 05/21 /2025 Survey CMS 209 form, none could be produced. 3. Interview with TS #2 at 10: 00 am 12/10/2025 confirmed that a policy and procedure for assessing personnel who were delegated as a TC, TS or GS could not be produced.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the 2025 American Proficiency Institute (API) proficiency test (PT) binders for events two (2) and three (3), no evidence of performance evaluation for Chemistry, Hematology, Microbiology or Blood Bank could be produced. Review of the attestation forms for 2024 events #2 and #3 revealed no Laboratory Director (LD) or LD designee had attested to the performance of the PT samples, treating them the same way as patient samples. Findings include: 1. Upon review of all API PT binders for 2025, no performance evaluation reports could be found for events two (2) and three (3) for all four (4) specialties, including Chemistry, Hematology, Microbiology or Blood Bank. 2. Upon request for API PT performance evaluation reports for 2025 events two (2) and three (3), none could be produced. 3. Review of the attestations for Chemistry 2024 event #3, Hematology 2024 event #2 and Blood Bank 2024 event #3, revealed no LD signature or LD designee signature on the attestation form for each event. 4. Review of multiple failed PT events in 2024 & 2025 failed to demonstrate that the laboratory completed written corrective action (CA) and performed root cause analysis with QA, on these PT misses. 5. The laboratory reports performing 147,416 tests annually.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on multiple requests for a written Quality Assurance (QA) procedure and evidence of QA monitors and interview with testing personell (TP #5) and the Technical Supervisor (TS), the laboratory failed to complete and document corrective actions (CA) for the citation Dtag 5411 cited during survey 05/21/2025 and the Blood Banking (BB) event 10/19/2025, listed in the complaint received 12/01/2025. Findings include: 1. Upon request of written records, including amended reports for

	five (5) patients with PT/INR results that were reported incorrectly from 03/14/2025 - 05/21/025, described in the facility's plan of correction (PoC), for CFR 493.1252a, Dtag 5411, with a completion date of 06/30/2025, no amended patient reports or written communication about this error in PT/INR calculations with the providers for these patients, could be produced. 2. Upon request for written documentation of the CA performed for the Blood Bank incident on 10/19/2025, reported in the complaint received 12/01/2025, when a unit of blood was taken from the laboratory by nursing, without proper documentation or proper issuance, none could be produced. 3. In an email with the LD, received 12/12/2025, he recalled a phone call from the previous TS (TS #1) in regards to this incident. He stated her response was to contact nursing and meet with nursing leadership to educate staff on "the critically important correct process of issuing blood". 4. Also in this email from the LD on 12/12/2025, he described his computer view on his side, of the event, when reviewing utilization and transfusion reactions and said it showed no such incident on 10/19/2025. 5. TS #2 found one email by one of the testing personnel (TP #5), sent to TS #1 on 10/20/2025 at 7:46 am. TP #5 detailed the incident but no Quality Management Systems (QMS) submission was recorded or available for review during survey. 6. Interview with TS #2 at 10:30 am 12/10/2025 confirmed that no further CA or written documented follow up for the BB incident could be produced. 7. The laboratory reports performing 667 BB assays and 489 PT/INR assays annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manuals, Quality Control (QC) records, calibration records and interview with testing personel (TP #4), the laboratory failed to monitor and evaluate the overall analytic system and correct identified problems. Findings include: 1. See D5401, D5421, D5429, D5439, D5441, D5463, D5469, D5471
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the 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 the laboratory's policies and procedures for Blood Bank (BB) and Microbiology and interview with the Testing Personnel (TP) and the Technical Supervisor (TS), the laboratory failed to have an approved procedure in place for the TechLab C. Diff Quik Chek Complete test kit implemented in 2025, the potassium

	hydroxide (KOH) wet prep performed by Obstetrics providers, and multiple policies and procedures in Blood Bank (BB). Findings include: 1. Upon request for a written procedure for the TechLab C. Diff Quik Chek Complete test kit implemented in 2025 none could be produced. 2. Upon request for a written procedure for KOH wet preps, performed in the laboratory, by Obstetrics providers, none could be produced. 3. Upon request for the Blood Bank procedure manual, it was revealed that the manual contained procedures that were outdated (2013) and not signed by the current LD. These include: a. Procedure for Fresh Frozen Plasma (FFP) - no current LD signature and the procedure references AABB 19th edition (1999) b. Procedure for resolving ABO discrepancies - no current LD signature and the procedure references AABB 15th edition (pre 1999). 4. Interview with TP#4 at 9:00am (C. diff interview) and again at 12:30 pm (KOH interview) on 12/10/2025, confirmed there was no procedure for the C. diff QuikChek Complete test kit or the KOH procedure for Obstetrics personnel performing KOH wet mounts in the laboratory. 5. Interview with TS #2 at 10:30 am 12/10/2025 confirmed that this was the only printed BB procedure manual to her knowledge. 6. The laboratory reports performing 31 C. Diff Quik Chek tests, 667 Blood Bank related assays and an unknown number of KOH preps annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to produce documentation of verification of the performance specifications on the Abaxis Picollo chemistry analyzer and Sysmex XN-1000 (serial # 29794) hematology analyzer for cerebral spinal fluid (CSF). Findings include: 1. Upon request for written documentation of validation and implementation for the Abaxis Picollo Chemistry analyzer, none could be produced. 2. Upon request for evidence of written documentation of validation of the Sysmex XN - 1000 (when testing CSF), none could be produced. 3. Interview with TP#4 at 3:00pm on 12/09/2025 and TC #2 at 3: 30pm on 12/09/2025 confirmed no evidence of validation could be produced for either instrument. 4. The laboratory reports performing 101 Picollo chemistry tests annually, and an unknown number of CSF tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the maintenance records for the Abbott iSTAT analyzers and the

	Cepheid GeneXpert analyzer, and interview with Testing Personnel (TP), the laboratory failed to ensure manufacturer's guidelines for semi-annual maintenance was performed and documented as required. Findings include: 1. Upon review of the maintenance records for the Abbott iSTAT analyzers located in the Emergency Medical Services area (EMS) for 2024 and 2025, it was noted that the semi-annual maintenance activities recommended by the manufacturer were not documented. a. iSTAT serial number 312738 Semi-annual maintenance was not documented for May 2025 and November 2025. Thermal Probe maintenance was not documented for November 2025. iSTAT serial number 326307 Semi-annual maintenance was not documented for November 2025 Thermal Probe maintenance was not documented for November 2025 b. Interview with TP#4 on 12/9/2025 at 3:00pm confirmed findings. c. The laboratory reports performing 260 Abbott iSTAT chemistry panels annually. 2. Upon review of the maintenance records for the Cepheid GeneXpert analyzer for 2025, it was noted that the quarterly and annual maintenance activities recommended by the manufacturer were not documented. a. Interview with TP#4 on 12/9/2025 at 3:00pm confirmed these findings. b. The laboratory reports performing 846 Cepheid GeneXpert molecular tests annually.
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: Based on review of the laboratory's Chemistry records and interview with the testing personnel (TP) and the Technical Consultant (TC), the laboratory failed to ensure the calibration verification procedure was performed according to manufacturer's instructions. Findings include: 1. Upon review of calibration records for the Beckman AU480 Chemistry analyzer, put in use February 2025, no calibration documents since February 2025 could be produced. a. The procedure for calibration verification for the Beckman AU480 states that linearity should be performed every six (6) months. b. Interview with the TP #4 and TC #2 at 3:00pm 12/09/2025 confirmed that no calibration verification had been performed since the validation of the analyzer in February 2025. c. The laboratory reports performing 112,471 chemistry tests annually. 2. Upon review of calibration records for the iSTAT analyzer, no calibration documents could be produced for 2024 and 2025. a. The manufacturer's instructions for calibration verification for the iSTAT analyzer states that calibration verification

	should be performed every six (6) months. b. Interview with TC #2 at 3:00pm 12/09 /2025 confirmed that no calibration verification had been performed on any of the iSTAT analyzers in 2024 and 2025. c. The laboratory reports performing 260 Abbott iSTAT chemistry panels annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on interview with Testing Personnel (TP), and request of Quality Control (QC) records for the Beckman AU480 chemistry analyzer, Abaxis Picollo chemistry analyzer and the TechLab C. Diff Quik Chek Complete test kit, it was revealed that monthly Beckman AU480 QC was not being monitored over time for accuracy and precision of test performance, environmental conditions and variance in operator performance and QC for the Abaxis Picollo chemistry analyzer and TechLab C. Diff Quik Chek Complete test kit was not being documented when performed. Findings include: Beckman AU480 Chemistry Analyzer: 1. Interview with TP#4 at 3:00pm on 12/09/2025 confirmed that QC performed on the Beckman AU480 analyzer was stored on the analyzer software and documentation of monitoring QC performance was not being reviewed. 2. Upon request for documentation of QC monitoring none could be produced. 3. The laboratory reports performing 112,471 core chemistry tests annually. Abaxis Picollo Chemistry Analyzer: 1. Review of QC documents submitted for review revealed that QC was not being documented. 2. Interview with TP#4 at 9: 00am on 12/10/2025 confirmed that QC performed for the Abaxis Picollo Chemistry analyzer was not being documented. 3. The laboratory reports performing 101 Picollo chemisrey tests annually. C. Diff Quik Check complete tests 1. Upon request for written QC documentation for the C. Diff Quik Check Complete test kit, none could be produced. 2. Interview with TP#4 at 9:00am on 12/10/2025 confirmed that no written documentation of QC performed on the C. Diff Quik Check test kit could be produced. 3. The laboratory reports performing 31 C. Diff Quik Chek tests annually.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) (d)(7) Over time, rotate control material testing among all operators who perform the test. This STANDARD is not met as evidenced by: Based on interview with Testing Personnel (TP), and review of Quality Control (QC) records for the Abbott iSTAT analyzers, it was revealed that monthly Abbott iSTAT QC was not being rotated amongst all TP who perform testing using the Abbott

	iSTAT analyzer. Findings include: 1. Review of QC records revealed that the operators in the Emergency Medical Service (EMS) area and Respiratory Therapists (RT), were not required to participate in QC testing of the Abbott iSTAT analyzer designated for their use. 2. Interview with TP#4 at 3:00pm on 12/09/2025 confirmed the staff located in the laboratory were performing the QC on the Abbott iSTAT analyzers monthly. 3. The laboratory reports performing 260 Abbott iSTAT chemistry panels annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to have a system in place to verify the acceptability of all Quality Control (QC) materials. Findings include: 1. Upon request for documentation of QC implementation for the Beckman AU480 Chemistry analyzer in 2025 to date, none could be produced 2. Upon request for a policy on verification of acceptability of all QC materials in Chemistry, none could be produced. 3. Interview with TP#4 at 3:00pm on 12/09/2025 and TC #2 at 3:30pm on 12/09/2025 confirmed there was no policy for QC implementation in Chemistry. 4. The laboratory reports performing 112,471 Chemistry tests annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to have a system in place to confirm that each new lot number of reagent received performs within specifications established by the laboratory for the test procedure. Findings include: 1. Upon request for written documentation of new reagent lot numbers received for the Beckman Access 2 and Beckman AU480 chemistry analyzers for 2024 and 2025 to date, none could be produced. 2. Upon request for a policy for

	verification of acceptability of all new reagent lot numbers on the Beckman Access 2 and Beckman AU480 chemistry analyzers, none could be produced. 3. Interview with TP#4 at 3:00pm on 12/09/2025 and TC at 3:30pm on 12/09/2025 confirmed there was no policy for verification of acceptibility of all new reagent lot numbers. 4. The laboratory reports performing 112,471 chemistry tests annually.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) records for the Beckman Access 2 chemistry analyzer and Abbott iSTAT analyzer, and interview with Testing Personnel (TP), the laboratory failed to ensure QC results were documented as required. Findings include: 1. Upon review of the QC records for the Access 2 chemistry analyzer for dates 06/28/2025 through 11/30/2025, it was noted that the QC documentation requirement was not followed. a. Daily QC review of the Access 2 analyzer revealed the following: For dates 06/28/2025 through 11/30/2025 daily QC was not documented on dates 07/24/2025 through 08/15/2025 and 08/20/2025 through 08/29/2025 for all analytes on the Access 2 analyzer. 2. Upon review of the QC records for the two (2) iSTAT analyzers located in the Emergency Medical Services area (EMS) for 2024 and 2025, it was noted that the QC documentation requirement was not followed. a. Review of the QC log presented during the on-site survey for the EMS iSTAT analyzers revealed the following: i. iSTAT serial number 312738, monthly QC documentation was missing for dates: December 2024 June 2025 July 2025 October 2025 November 2025 ii. iSTAT serial number 326307, monthly QC documentation was missing for dates: July 2025 October 2025 November 2025 3. Interview with TP#4 on 12/9/2025 at 3:00pm confirmed these findings. 4. The laboratory reports performing 260 iSTAT chemistry tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures for Chemistry and Microbiology and interview with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to have a procedure or system in place to evaluate testing when the same analyte is tested on different test platforms twice a year. Findings include: 1. Upon request for written documentation of test comparison results for 2024 and 2025 for the Abbott iSTAT comparison to the Beckman AU480 Chemistry analyzers, as well as Abaxis Picollo comparison to the Beckman AU480 Chemistry analyzers, none could be produced. 2. Upon request for written documentation of test comparison results for 2025 for the Cepheid GeneX Clostridium difficile test with comparison to C. Diff Toxin QuikChek Complete test,

	none could be produced. 3. Upon request for a policy on comparison of test results for analytes that are tested on multiple platforms, none could be produced. 4. Interview with TP#4 at 3:00pm on 12/09/2025 and TC #2 at 3:30pm on 12/09/2025 confirmed there was no policy on comparison of test results for analytes that are tested on multiple platforms. 5. The laboratory reports performing 112,471 chemistry tests and and 31 C. difficile assays annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on interview with Testing Personnel (TP), and request of Quality Control (QC) records for the Beckman AU480 chemistry analyzer, it was revealed that Beckman AU480 QC did not have corrective action (CA) documented for actions taken when QC failed. Findings include: 1. Upon request for written CA for failed QC, none could be produced. 2. Interview with TP#4 at 3:00pm on 12/09/2025 confirmed that QC performed on the Beckman AU480 analyzer was stored on the analyzer software and it is not possible to document any corrective action performed when QC fails. 3. The laboratory reports performing 112,471 chemistry tests annually.
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 review of Respiratory Testing Personnel (RT - TP), Emergency Medical Services Testing Personnel (EMS - TP) and laboratory Testing Personnel (TP) training and competency records, and interview with the current Technical Consultant (TC #2), TC #1 failed to fulfill the duties of the position of TC. Findings include: 1. See D6046, D6053
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

	This STANDARD is not met as evidenced by: Based on lack of written annual competency assessments in 2025 to date, for two (2) out of two (2) RT-TP and incomplete competency assessments in 2024 and 2025 to date for twelve (12) out of twelve (12) EMS-TP, six(6) laboratory testing personnel (TP) and two (2) hospital MD's in 2025 to date, and interview with the Technical Consultant (TC #2), TC #1 failed to ensure annual competency assessments for the Abbott iSTAT analyzer, the Techlab C. diff Quik Chek Complete test and the potassium hydroxide (KOH) wet mount procedure were performed on all TP using any of these test systems. Findings include: 1. Upon request for competency assessments for RT-TP, and EMS-TP in 2024 and 2025 to date, it was revealed that two (2) out of two (2) RT - TP lacked any record of competency assessment on the Abbott iSTAT analyzer in 2025, and twelve (12) out of twelve (12) EMS-TP had incomplete competency assessment records on the Abbott iSTAT analyzer in 2024 and 2025. 2. Upon request for competency assessments for six (6) laboratory testing personnel (TP) using the TechLab C. diff Quik Check Complete test, none coulds be produced. 3. Upon request for bi-annual verification for the potassium hydroxide (KOH) wet mount test for two (2) out of two (2) MD's, none could be produced. 4. Interview with the TC #2 at 11:00am on 12/09/2025 confirmed no written competency assessments for any of these TP could be produced. TC#2 also confirmed that twelve (12) of the EMS TP had been conducted by an unqualified and non-delegated individual,(LP), no longer employed there. 5. The laboratory reports performing 260 iSTAT chemistry panels and 31 C.diff Quik Chek Complete tests annually. The number of KOH wet mounts could not be determined while on site.
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 lack of written training and competency assessment documentation for Testing Personnel (TP) responsible for performing the TechLab C. Diff Quik Chek Complete test kit in 2025, and the potassium hydroxide (KOH) wet mount procedure and interview with the Technical Consultant (TC #2), TC #1 failed to ensure initial and semi-annual competency assessments were completed during the first year of testing patient specimens. 1. Upon request for written competency assessments for TP in the laboratory, it was revealed that six (6) out of six (6) TP lacked any record of initial and semi-annual training assessment on the TechLab C. Diff Quik Chek Complete test kit since implemented in 2025. 2. Upon request for written competency assessments for two (2) out of two (2) medical doctors (MD's) from Obstetrics, it was revealed that the two (2) MD's lacked any record of initial and semi-annual training assessment for the KOH procedure. 3. Interview with the TC #2 at 9:00am on 12/10 /2025 confirmed that no written training or competency assessments for the C. diff Quik Chek Complete test could be produced. 4. Interview with the Technical Consultant (TC #2) at 10:30 am on 12/10/2025 confirmed that no training or competency records for the two (2) MD's performing KOH testing could be found. 5. The laboratory reports performing thirty one (31) C. Diff Quik Chek Complete tests annually. The number of KOH tests performed could not be determined while on site.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of all testing personnel (TP) competency records, review of Proficiency testing (PT) records, lack of Quality Control (QC) records, performance verification records, maintenance records and lack of a written Quality Assurance (QA) plan with evidence of QA monitors, the Laboratory Director (LD) failed to fulfill the position of LD. Findings include: 1. See D6092, D6102, D6103, D6107, D6092, D6093
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of the 2024 & 2025 American Proficiency Institute (API) proficiency test (PT) binders for events one (1), two (2) and three (3), review of CASPER 0155 report, and interview with the Technical Consultant (TC), it was revealed that the laboratory director (LD) failed to ensure complete corrective action (CA) was performed and documented for analytes with failed or unacceptable results on forty two (42) PT analytes. Findings include: 1. Upon review of the PT records presented for review during on site survey, it was revealed that the LD failed to ensure complete CA was documented for unacceptable or failed PT results for PT event one (1) in 2024. a. 2024 Chemistry-Core event #1, incomplete CA documentation for analytes: pO2 - 60% Troponin - 40% AST - 80% Blood gas PH - 80% ALT - 80% Albumin - 80% PCO2 blood gas - 80% Blood Urea Nitrogen (BUN) - 80% b. 2024 Chemistry-Miscellaneous event #1, incomplete CA documentation for analytes: Cerebral Spinal Fluid (CSF) Glucose - 67% Cerebral Spinal Fluid (CSF) Protein - 67% c. 2024 Microbiology event #1, incomplete CA documentation for analytes: SARS-CoV2 - 50% d. 2024 Blood Bank event #1, incomplete CA documentation for analytes: Antibody Detection - 80% 2. Upon review of the PT records presented for review during on site survey, it was revealed that the LD failed to ensure complete CA was documented for unacceptable or failed PT results for PT event two (2) in 2024. a. 2024 Blood Bank event #2, incomplete CA documentation for analytes: Antibody Detection - 80% b. 2024 Hematology event #2, incomplete corrective action for PT /INR testing - 60% c. 2024 Chemistry event #2, incomplete corrective action for AST testing - 80% 3. Upon review of the PT records presented for review during on site survey, it was revealed that the LD failed to ensure complete CA was documented for unacceptable or failed PT results for PT event three (3) in 2024. a. 2024 Chemistry-Core event #3, incomplete CA documentation for analytes: HCG - 80% AST - 80% HDL - 80% LDL - 80% pCo2 - 80% pO2 - 80% b. 2024 Blood Bank event #3, incomplete CA documentation for analytes: Antibody Detection - 60% Compatibility Testing - 80% 4. Upon review of the PT records presented for review during on site survey, it was revealed that the LD failed to ensure complete CA was documented for

	unacceptable or failed PT results for PT event one (1) in 2025. a. 2025 Chemistry event #1, incomplete CA documentation for analytes: Albumin - 80% ALT - 80% Hemoglobin A1C (HgbA1C) - 60% BUN - 80% Digoxin - 80% 5. Upon review of the PT records presented for review during on site survey, it was revealed that the LD failed to ensure complete CA was documented for unacceptable or failed PT results for PT event two (2) in 2025. a. 2025 Chemistry event #2, incomplete CA documentation for analytes: HgbA1C - 80% Iron - 80% Blood Alcohol - 80% 6. Upon review of the PT records presented for review during on site survey, it was revealed that the LD failed to ensure complete CA was documented for unacceptable or failed PT results for PT event three (3) in 2025. a. 2025 Chemistry event #3, incomplete CA documentation for analytes: Blood Gas PH - 80% Blood Gas PO2 - 60% Blood Gas CO2 - 60% Iron - 60% Free TY - 80% HCG - 80% TSH - 60% Vitamin B12 - 80% Blood Alcohol - 80% Digoxin - 80% Uric Acid - 80% 7. Upon request for the laboratory's procedure for CA, for unacceptable or failed PT results, none could be produced. 8. Interview with TC #2 at 3:00pm on 12/09/2025 confirmed the LD failed to ensure complete CA documentation was performed for all PT analytes with failed or unacceptable results. 9. The laboratory reports performing 112,471 chemistry tests, 33,285 hematology tests, 846 microbiology tests and 667 blood bank tests annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures for Quality Assessment (QA) for all phases of laboratory testing and interview with the Technical Supervisor (TS #2), the Laboratory Director (failed to ensure a QA plan was in place and being followed by all laboratory personnel. Findings include: 1. See D5239
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 evidence of appropriate education and experience for all Emergency Medical Services testing personnel (EMS-TP) listed on the current CMS-209 form, performing moderately complex testing and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure all EMS-TP staff were qualified to perform testing on the Abbott iSTAT chemistry analyzer. Findings include: 1. Upon request for education documents for the thirteen (13) EMS-TP listed on the CMS-209 form, it was revealed that seven (7) out of thirteen (13) lacked any educational documents on site. a. Education documents were not produced for EMS-TP #3, EMS-TP #4, EMS-TP #5, EMS-TP #6, EMS-TP #7, EMS-TP #12, EMS-TP #13. 2. Interview with TC #2 at 10:00am on 12/10/2025 confirmed they were unable

	to locate education documents for the EMS-TP listed above. 3. The laboratory reports performing 260 Abbott iSTAT chemistry panels annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 policies and procedures and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure there was an approved policy and procedures for monitoring the performance of all laboratory personnel who participate in any of the three (3) phases of testing, including pre-analytic, analytic and post-analytic. Findings include: 1. Request for the lab's policy and procedures for assessing competency of all laboratory personnel, none could be produced. 2. Interview with TS #2 at 10:00 am on 12/10/2025 confirmed that neither an approved and dated policy or procedure for monitoring individuals that perform any of the three (3) phases of laboratory testing could be found. 3. The laboratory reports performing 147,416 laboratory tests annually.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on multiple requests for a written designation of duties for all persons involved in any of the three (3) phases of testing in the laboratory (pre-analytic, analytic and post analytic) and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to specify, in writing, the laboratory testing each individual was approved to perform or report. Findings include: 1. Upon request from TS #2 for a written designation of duties (twice), none could be produced. 2. Interview with TS #2 at 10:30 am on 12/10/2025, confirmed that no current written designation of duties by the LD could be produced. 3. The laboratory reports performing 147,416 assays annually.