Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2122931	12/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hospitals Of Providence Transmountain Campus, The	2000 Transmountain Rd, Lower Level, El Paso, 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 upon findings made during an onsite validation survey completed December 7, 2023 the laboratory failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1250 Condition: Analytic Systems: 493. 1403 Condition: Laboratories performing moderate complexity testing; laboratory director: 493. 1409 Condition: Laboratories performing moderate complexity testing; technical consultant: 493. 1421 Condition: Laboratories performing Moderate Complexity Testing; testing personnel:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, manufacturer instructions for use (IFU), laboratory quality control (QC) records, laboratory worksheets, and confirmed in interview, the laboratory failed to retain the "Spinalscopics Spinal Fluid Cell Count Control/Level 1 & 2" IFU's for the lot-specific QC acceptability criteria for level one and level two body fluid (BF) QC from January 2022 to October 2023. The findings included: 1. Policy titled "Record Retention Policy" included the following information: "Type of Record/Material - Retention Period Quality control records - 2 years (5 years for transfusion medicine)" 2. Review of laboratory policy titled "Body Fluid Analysis", section IV. "Quality Control" stated the following: "A. One level of control is counted in duplicate per 8 hour shift. The level of control used depends on the shift: 1st shift - Level I 2nd and 3rd shift - level II B. ... If results are out of limits, re-mix and load a new Hemocytometer. If expected results are still out of range, open a new vial and start over." 3. Review of the "Spinalscopics Spinal Fluid Cell Count

	Control/Level 1 & 2", section "Limitations" had the following statement: "Any future changes made by the manufacturer of a test system may give different values from the indicated range." 4. Review of the laboratory worksheet titled "Body Fluid Hemocytometer Counts" did not include record of the quality control lot numbers in use on day of testing or the expected acceptability range. The surveyor asked about the acceptable expected ranges for the cell count control. The technical consultant (TC) 1 stated the laboratory used the expected range on the back of the "Spinalscopics Spinal Fluid Cell Count Control/Level 1 & 2" instructions for use. Surveyor queried for the 2022 to October 2023 IFUs, to assess the QC acceptability, and none was provided. 5. In an interview on 12/5/2023 at 14:15, in the conference room, TC 1 stated that the laboratory did not retain the "Spinalscopics Spinal Fluid Cell Count Control/Level 1 & 2", from January 2022 to October 2023.
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 laboratories policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory failed to meet the applicable analytic systems requirements for Bacteriology, Cytology and Hematology in 2022 and 2023. The laboratory failed to ensure expired media was not used for patient testing in Bacteriology. (See D5417) The laboratory failed to test quality control materials each day of patient testing when using the ImmunoCardSTAT Mono Test. (See D5449) The laboratory failed to test at least one level of quality control each 8 hours when performing manual cell counts using a hemacytometer. (See D5543) The laboratory failed to test quality control materials each time patient specimens were tested using the Stago FDP Plasma kit. (See D5547) The technical Supervisor for Cytology failed to establish a maximum workload limit for five of five testing personnel performing primary screening of Cytology specimens. (See D5633)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 laboratory's policies/procedures, random patient sample processing and equipment decontamination logs for 2023, and staff interview, the laboratory failed to document performance of 2 of 4 histology procedures to prevent cross-contamination between cases, as per its own protocols, in 11 months reviewed

	from January to November 2023. Findings included: 1. Review of laboratory procedure "Quality Management Plan" (document PH:01, last reviewed 05/01/2023) revealed: "Prevention of Cross-Contamination ANP.11680 ... ii. The pathologist will clean their forceps and scalpel blades by wiping or rinsing between each case in addition to cleaning their cutting surfaces between each case. ... iv. Cryostat blades will be discarded after use per case." 2. Review of random patient sample processing and equipment decontamination logs for 2023 revealed the laboratory did not have documentation of equipment and cutting surface cleaning or Cryostat blade replacement between cases. 3. In an interview on 12/06/2023 at 1510 hours in the laboratory's conference room, the facility's Testing Person number 2 (as indicated on submitted Form CMS 209), confirmed the laboratory did not document cleaning of cutting instruments/surfaces or Cryostat blade replacement.
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 a review of manufacturer's instructions, laboratory documents, and confirmed in interview, the laboratory failed to ensure the selection of normal results were obtained from normal patients used in lot rollover studies for the mean normal patient (MNPT) results for the new lot Innovin Protime (PT) reagents put in use on 3 /12/2023 for two of two analyzers used in coagulation testing: the Sysmex CA660 and the Sysmex CS2500. The findings included: 1. In a tour of the laboratory on 12/5 /2023 at 09:20 hours the hematology department had the following two analyzers in use for coagulation (coag) testing: CA660 - SN13437 CS2500 - SN21437 2. Review of the Sysmex CS2500 System "Installation Guide", section XV "Lot Roll Over Procedure", subsection "Verification of Reference Range" stated the following: "- 20 Normal Individuals - 10 males and 10 females representing reference population. 20 is the minimum requirement for a statistically valid study ... Note: Assess medication history. After review of data, history may be used for excluding aberrant results. - Calculate mean and 2 SD range. - MNPT for INR calculation must be the geometric mean." 3. Review of the Sysmex CA660 Series "Installation Guide", section XIV "Reagent Lot Roll-Over Studies", subsection I "Verification of Reference Range" stated the following: "A. 20 Normal Individuals - 10 males; 10 females spanning age range. 20 is the minimum requirement for a statistically valid study. ... - Note medication history. After review of data, history may be used for excluding questionable results that can be attributed to medications. ... C. Calculate mean and 2 SD range. D. MNPT for INR calculation must be the geometric mean." 4. Review of the laboratory lot rollover documents for the new Innovin PT reagent (Lot#549795, exp 4/29/2024), put in use 3/16/2023 on the Sysmex CS-2500 and the CA-660, did not include the evaluation of patient medication history. In an interview on 12/6/2023 at 11:30 hours, in the hallway, the technical consultant (TC)1 stated the laboratory used normal results for the study and that an evaluation of patient medication history, or health, was not used as a criterion for determining inclusion in the lot rollover MNPT studies. 5. In an interview on 12/6/2023 at 12:00 hours, in the conference room, the

	technical consultant (TC) 1 and the administrative director stated a patient evaluation was not performed to demonstrate that the results obtained for the lot rollover studies were from normal patients.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer operating specifications for the Cryostat and microscope instruments in use in the Histology/Cytology department, review of random Histology/Cytology environment monitoring logs for 2023, laboratory test volumes and staff interview, the laboratory failed to document monitoring of room humidity and/or temperature for 3 of 3 rooms where the Cryostat and/or microscope instruments were in use, in 11 months reviewed from January to November 2023. Findings included: 1. Review of manufacturer operating specifications for the Tissue Tek Cryo3 Flex Cryostat (document 0007662-01 Rev. B, revised 25 July 2016) revealed: "Operating Environment: Temperature: 15C [Degrees Celsius] ... to 35C ... Relative Humidity: 30-85%[percent] (non-condensing)" 2. Review of manufacturer operating specifications for the Carl Zeiss Microscope (document Axio Vert. A1) revealed: "Operation: Permissible ambient temperature ... ... +5 C to +40 C Maximum permissible humidity ... ... 75%" 3. Review of random Histology /Cytology environment monitoring logs for 2023 revealed there was no documentation of humidity and/or temperature monitoring for the following rooms where the Cryostat and/or microscope instruments were in use: a. Frozen Room: There was no documentation of humidity monitoring. Frozen Room Equipment: Carl Zeiss Microscope serial number (SN):3135010037 Tissue Tek Cryo3 Flex Cryostat SN: 62010117-0916 b. Pathologist's Office (Room 1): There was no documentation of humidity or temperature monitoring. Room 1 Equipment: "Double headed" Carl Zeiss microscope Serial Number (SN) 3321010047 c. Pathologist's Office (Room 2): There was no documentation of humidity or temperature monitoring. Room 2 Equipment: "Double headed" Carl Zeiss microscope SN 3321003816 "Single headed" Carl Zeiss microscope SN 3135010041 4. Review of laboratory's submitted test volumes revealed the laboratory performed 20,033 histology/cytology examinations annually. 5. In an interview on 12/06/2023 at 1620 hours in the laboratory's conference room the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents), confirmed the laboratory did not monitor temperature and/or humidity in Frozen section room or pathologists' offices.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: A. Based on surveyor's observations and staff interview, the laboratory failed to ensure expired media was not used in processing samples for two of two microbiology cultures observed requiring liquid Remel THIO (Thioglycolate) media, wound and body fluid cultures. Findings included: 1. Surveyor's observations on 12/06/2023 at 1405 hours in the laboratory revealed the following two patient samples inoculated in expired liquid THIO media incubating in the microbiology 35C (Degrees Celsius) aerobic incubator: Sample:320-MB-23-019854 Patient MRN (Medical Record Number): 5110744 Culture: Wound Collected: 12/06/2023 Inoculated THIO broth lot number: 715713 Inoculated THIO broth expiration date: 2023-10-03 Sample:320-MB-23-019789 Patient MRN:5138879 Culture: Body Fluid Collected: 12/06/2023 Inoculated THIO broth Lot number: 715713 Inoculated THIO broth expiration date: 2023-10-03 2. In an interview on 12/06/2023 at 1405 hours in the laboratory, the facility's Testing Person number 2 (as indicated on submitted Form CMS 209), after viewing the patient's inoculated samples, confirmed the findings. B. Based on surveyor's observations and staff interview, the laboratory failed to ensure four of four bottles of expired Cytoseal 60 reagent were not used in cytological and histological preparations from October through December 6, 2023. Findings included: 1. Surveyor's observations on 12/06/2023 at 1457 hours in the laboratory revealed four bottles of expired Cytoseal 60 reagent in the Grossing Room's flammables' cabinet. Lot number: 111800 Expiration date: 09/2023 2. In an interview on 12/06/2023 at 1500 hours in the laboratory the facility's Testing Person number 8 (as indicated on submitted Form CMS 209), when asked, stated the laboratory used the expired Cytoseal 60 in slide preparations for approximately 80-90 histology/cytology cases since September 2023. He also stated that no other unexpired Cytoseal 60 reagent was available for use in the laboratory. 3. In an interview on 12/06/2023 at 1505 hours in the laboratory, the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents), confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: A. Based on review of laboratory's stain maintenance protocols, random stain reagent maintenance records for 2022 and 2023 and staff interview, the laboratory failed to follow its own protocols for documenting weekly and daily stain reagent change for two of two stains, Hematoxylin and Eosin (H&E) and Diff Quick stains, used in histology and cytology departments in 2022 and 2023. Findings included: 1. Review of laboratory's stain maintenance protocol/log "H&E STAIN LINE_FROZEN ROOM" (Version 2021A) revealed: "Stain line is changed weekly when in use. Water is changed daily after each use." And: "Changed CH Rotated R Filtered F Checked V (check mark)" 2. Review of laboratory's stain maintenance protocol/log "DIFF

	QUICK STAIN" (Version 2021 A) revealed: "Stain line is changed weekly at minimum. Water is changed daily after each use." And: "Changed CH Rotated R Filtered F Checked V" 3. Review of random stain reagent maintenance records for 2022 and 2023 revealed the following weekly and daily stain reagent changes not being documented: H&E STAIN LINE_FROZEN ROOM January 17-21, 2022: No documentation of stain line weekly change (reagents documented as F or V) No documentation of daily water changes (documented as V) August 15-19, 2022: No documentation of stain line weekly change (reagents documented as F or V) No documentation of daily water changes (documented as V) DIFF QUICK STAIN August 22-26, 2022: No documentation of stain line weekly change (reagents documented as V) No documentation of water daily changes (documented as V) April 10-14, 2023: No documentation of stain line weekly change (reagents documented as V) No documentation of water daily changes (documented as V) 4. In an interview on 12/06/2023 at 1510 hours in the laboratory's conference room, the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents), confirmed the findings. B. Based on surveyor's observations, review of the manufacturer instructions for use, random microscope maintenance logs for 2023, laboratory's policies/procedures and staff interview, the laboratory failed to document daily maintenance for 3 of 3 pathologists' microscopes used in histologic and cytologic examinations from January to December 2023. Findings included: 1. Surveyor's observations on 12/06/2023 at 1515 hours in Pathologists' offices revealed the following microscopes were being used for histologic and cytologic examinations: Room 1: One "double headed" Carl Zeiss microscope Serial Number (SN) 3321010047 Room 2: One "double headed" Carl Zeiss microscope SN 3321003816 One "single headed" Carl Zeiss microscope SN 3135010041 2. The laboratory was asked for a user manual/instruction for use for the Carl Zeiss microscopes and no such document was available for review prior to survey exit. 3. Review of laboratory's random microscope maintenance logs for 2023 revealed documentation of daily microscope maintenance for the other microscopes used for histologic and cytologic examinations. There was no documentation of daily microscope maintenance for the above microscopes found in Pathologists' offices. 4. Review of laboratory's policy "Instrument and Equipment Maintenance" (document PH:18, last reviewed 05/01 /2023) revealed: "Equipment is assessed daily and corresponding logs filled out to preserve the integrity of the equipment/instrument." 5. In an interview on 12/06/2023 at 1620 hours in the laboratory's conference room, the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents) confirmed the laboratory did not document daily maintenance for the pathologists' microscopes.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions for use, laboratory's policies /procedures, quality control (QC) records for 2023, patient test logs and staff interview, the laboratory failed to document ImmunoCard STAT! Mono Test QC each day of patient testing for six of twenty-four days from February through May 2023.

	Findings included: 1. Review of manufacturer instructions for use for the ImmunoCard STAT Mono Test (document 755725) revealed: "CLIA Complexity: ... Serum or Plasma - Non-waived" And, "External Quality Control ... Quality Control requirements should be established in accordance with local, state, and federal regulations or accreditation requirements." 2. Review of laboratory's policy "Meridian Bioscience ImmunoCard STAT! Mono Test" (document MB 6.8, last reviewed 05/16 /2023) revealed: "External Quality Control Testing Frequency: Two sets of external QC, a positive and a negative control included with the kit are run with each new lot, new shipment, in accordance with the manufacturer, state, local and federal regulations." 3. In an interview on 12/6/2023 at 1330 hours in the laboratory the Testing Person number 2 (as indicated on submitted Form CMS 209) stated the laboratory uses serum for the STAT! Mono Test, making it a non-wiaved test requiring QC each day of testing, and that the laboratory did not perform Individualized Quality Control Plan studies to reduce frequency of QC performance. 4. Review of laboratory's 2023 QC records for the ImmunoCard STAT Mono Test and patient test logs revealed the following six of twenty-four reviewed days patient testing was performed without documentation of QC: Date: Patient tested (MRN): 02 /16/2023 5125011 03/23/2023 5036869 04/04/2023 5038248 04/05/2023 5038247 04 /27/2023 5071684 05/02/2023 5098622 5. In an interview on 12/06/2023 at 1400 hours in the laboratory, the facility's Testing Person number 2 confirmed the findings. Key: MRN = Medical Record Number CMS = Centers for Medicare and Medicaid
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on a review of laboratory policy, laboratory quality control records, and patient test results, the laboratory failed to ensure that QC was performed every 8 hours for body fluid cell counts on the C-Chip hemocytometer for nine of nine patients reviewed in random weeks in August, November, December 2022 and February 2023. The findings included: 1. Review of the laboratory policy titled "Body Fluid Analysis", section IV "Quality Control" stated the following: "A. One level of control is counted in duplicate per 8 hour shift." In an interview on 12/16/2023 at 11: 30 hours, in the conference room, the technical consultant (TC) 1 stated that the laboratory did not currently have staff for 8-hour shifts and that testing personnel were staffed in 12-hour shifts. 2. A review of the laboratory worksheets titled "Body Fluid Hemocytometer Counts" for random weeks in August, November, December 2022 and February 2023 had the following four instances where QC elapsed 8 hours: August 2022 8/8/2022 No QC was documented on 8/8/2022 Patient 005114598, performed at 05:55 hours Patient 005114598, performed at 07:15 hours Patient 005004120, performed at 17:00 hours November 2022 11/1/2022 Level 1 QC performed at 11:05 hours Patent 005119128, performed at 20:20 hours, 1 hour 20 minutes lapse of 8 hour QC. December 2022 12/28/2022 Level 1 QC performed at 11: 15 hours (next QC due 19:15) Patient 005109899, verified in LIS at 19:23 MST, 8 minutes lapse of 8 hour QC Patient 005122564, verified in LIS at 20:00 MST, 45 minutes lapse of 8 hour QC Patient 005122480, verified in LIS at 21:14 MST, 1 hour 59 minutes lapse of 8 hour QC February 2023 2/6/2023 Level 1 QC performed at 00:

	00 hours Patient 005069769, performed at 14:55 hours, 6 hours 55 minutes lapse of 8 hour QC Patient 005068586, performed at 15:10 hours, 7 hours 10 minutes lapse of 8 hours QC 3. In an interview on 12/16/2023 at 11:50 hours, in the conference room, TC1 confirmed the lapse in the eight-hour QC requirement for manual cell counts on the hemocytometer for the above days. II. Based on review of laboratory worksheets, laboratory patient results, and confirmed in interview, the laboratory failed to document the time of quality control performance for the "Spinalscopics Spinal Fluid Cell Count Control/Level 1 & 2" for four of nine days reviewed in November and December 2022, and February and May 2023. The findings included: 1. Review of the laboratory policy titled "Body Fluid Analysis", section IV "Quality Control" stated the following: "A. One level of control is counted in duplicate per 8 hour shift." 2. A review of the laboratory worksheet titled "Body Fluid Hemocytometer Counts" included a column for the record of date and time of test performance. In an interview on 12/5/2023 at 13:42 hours, in the conference room, technical consultant (TC) 4 stated the laboratory did not document QC for hemocytometer body fluid cell counts anywhere other than the "Body Fluid Hemocytometer Counts" worksheets. 3. Review of random weeks in November and December 2022, and February and May 2023 had the following 4 days where QC time was not documented on the "Body Fluid Hemocytometer Counts" worksheet: November 2022: 11/19/2022 - no documentation of time QC was performed Patient 005005195, verified in the LIS at 14:20 MST Patient 005119028, verified in the LIS at 16:03 MST Patient 005008647, verified in the LIS at 19:51 MST December 2022: 12/20/2022 - no documentation of time QC was performed Patient 005118224, sample one verified in LIS at 15:15 MST Patient 005118224, sample two verified in LIS at 15:19 MST Patient 005058931, verified in LIS at 15:32 MST Patient 005122177, verified in LIS at 15:51 MST February 2023: 2 /3/2023 - no documentation of time QC was performed Patient 005037301, verified in the LIS at 14:52 MST Patient 005002416, verified in the LIS at 14:36 MST Patient 005124215, verified in the LIS at 14:43 MST Patient 005087983, verified in the LIS at 17:06 MST May 2023: 5/31/2023 - no documentation of time QC was performed Patient 005120798, verified in the LIS at 10:07 MST Patient 005119417, verified in the LIS at 11:35 MST Patient 005130307, verified in the LIS at 14:14 MST Patient 005130030, verified in the LIS at 14:28 MST Patient 005125402, verified in the LIS at 19:40 MST 4. In an interview on 12/6/2023 at 11:55 hours, in the conference room, TC1 confirmed that the laboratory failed to ensure documentation of QC time for the hemocytometer body fluid cell counts for the above days.
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of manufacturer instructions for use, laboratory quality control (QC) worksheets, and patient test results, the laboratory failed to ensure that QC was performed with every patient tested for 8 of 17 patients tested for Fibrin Degradation Products (FDP) in six months reviewed, January, February, April, May, July, and August 2023. The findings included: 1. Review of the "Stago FDP Plasma kit instructions for use for the Qualitative and Semi-Quantitative Determination of FDP

	in Plasma for Latex Agglutination", section 9 "Procedure", subsection "Quality Control" had the following instructions: "Each time the patient's plasma dilutions are tested, include a positive and negative control in the test-run so as to have agglutination patterns for comparison." 2. Review of laboratory quality control (QC) worksheets and patient reports for January, February, April, May, July, and August 2023 had the following 8 patients with FDP testing performed without documentation of QC. February 2023: 2 patients with no documentation of QC. 2/17/2023, Patient MRN 005097691 2/22/2023, Patient MRN 005104098 April 2023: 1 patient with no documentation of QC. 4/18/2023, Patient MRN 005128158 May 2023: 2 patients with no documentation of QC. 5/19/2023, Patient MRN 005129796 5/23/2023, Patient MRN 005038247 July 2023: 2 patients 2 patients were tested for FDP on 7/10/2023 MRN 005132305, verified at 03:50 MDT MRN 005132298, verified at 09:50 MDT Quality control was performed on same day of testing with no documentation of time to determine QC acceptability for patient test results. August 2023: 1 patient with no documentation of QC. 8/26/2023, Patient MRN 005034080 3. In an interview on 12/6 /2023 at 14:55 hours, in the conference room, technical consultant (TC) 1 confirmed that QC was not documented for the above patients with FDP testing.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel's cytology screening workload records for 2023, policies/procedures and staff interview, the laboratory's Cytology Technical Supervisor failed to establish a maximum workload limit for five of five individuals who performed primary screening. Findings included: 1. Review of laboratory testing personnel's cytology screening workload records for 2023 revealed the laboratory documented daily workload for five of five individuals performing primary screening. 2. Further review of the workload records revealed there were no individual workload limits established for each of the five testing personnel performing primary screening. 3. Review of laboratory's policy "Cytology Screening" (document CYTO:10, last reviewed 05/01/2023) revealed: "Workload Policy ... Individual workload limits for each cytotechnologist will be set by the pathologist according to individual performance capabilities and reassessed at least every six months." There were no protocols in place for establishing individual workload limits. 4. In an interview on 12/07/2023 at 1120 hours in the laboratory's conference room, the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents) confirmed the findings.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by:

	Based on review of laboratory's policies/procedures, laboratory testing personnel's cytology screening workload records for 2023, submitted Form CMS 116 and staff interview, the laboratory failed to follow its own policy at least every 6 months for documentation of workload limit reassessment and/or adjustment for five of five cytology testing personnel performing primary screening. Findings included: 1. Review of laboratory's policy "Cytology Screening" (document CYTO:10, last reviewed 05/01/2023) section revealed: "Workload Policy ... Individual workload limits for each cytotechnologist will be set by the pathologist according to individual performance capabilities and reassessed at least every six months." 2. Review of laboratory testing personnel's cytology screening workload records for 2023 and submitted Form CMS 116 revealed the laboratory had five cytology testing personnel performing primary screening. 3. The laboratory was asked to provide documentation of 6 months' workload limit reassessment and/or adjustment for five of five cytology testing personnel performing primary screening, and no such documentation was available for review prior to survey exit. 4. In an interview on 12/07/2023 at 1130 hours in the laboratory's conference room, the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents) confirmed the findings.
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 review of laboratory's Histology quality control (QC) records for January to July 2023, policies/procedures, corrective action documentation, patient test logs and staff interview, the laboratory failed to establish and document corrective actions for unsatisfactory tissue section and stain quality for four of thirty weeks reviewed. Findings included: 1. Review of laboratory's Histology quality control (QC) records for January to July 2023 revealed the following weeks where tissue section and/or stain quality was documented as unsatisfactory: Week of January 16-22, 2023 Unsatisfactory ("U") Section Quality and Hematoxylin and Eosin (H&E) Stain was documented on Wednesday, Thursday and Friday. Comments documented: "H&E section from all week are too thick & over stained". Weeks of May 1-12, 2023 Monday through Friday (across all days) Section Quality had documented: "Thick sections. Example: SP23-1516 H&E Stain Quality had documented: "Thick sections and dark eosin staining". IHC(Immunohistochemical) Stain Quality had documented: "Poor too dark". Comments documented: "Unsatisfactory Section: -1516; Comments: B2, B5, B6 thick sections, dark staining". Week of May 29 to June 2, 2023 Monday through Friday (across all days) Section Quality had documented: "Too thick". H&E Stain Quality had documented: "Too dark (pink)". Week of July 17-21, 2023 Monday through Friday (for each of the days) Section Quality had documented: "U" (Unsatisfactory). H&E Stain Quality had documented: "U". Comments documented:" 07/17/23 - SP23-2310 - all sections too thick and overstained" And, " ...case sections

	are visibly thick almost to the point of being nondiagnostic". 2. Review of laboratory's policy "Slide Quality Control" (document PH:19, last reviewed 05/01/2023) revealed: "2. The pathologist reading microscopic examinations will fill out Q.C. log daily and document if there are any discrepancies, unsatisfactory or poor quality slides. a. Issues will be communicated with the histology department PRV, reconciled, and a Performance Improvement (P.I.) corrective action form may be issued." 3. Review of laboratory's corrective action records revealed there was no documentation of corrective action, P.I. forms and/or reconciliation of issues for the above unsatisfactory tissue section and stain quality instances. 4. Review of the laboratory's patient test logs for the weeks with unsatisfactory section and stain quality revealed patients' cases had histological examinations performed and were signed out by the pathologist: Week of January 16-22, 2023: Date: Total Cases Signed Out: 01/18/2023 49 01/19/2023 26 01/20/2023 22 Weeks of May 1-12, 2023: Date: Total Cases Signed Out: 05/01/2023 15 05/02/2023 18 05/03/2023 13 05/04/2023 22 05/05/2023 17 05/08 /2023 16 05/09/2023 23 05/10/2023 9 05/11/2023 25 05/12/2023 19 Week of May 29 to June 2, 2023: Date: Total Cases Signed Out: 05/29/2023 0 05/30/2023 30 05/31 /2023 24 06/01/2023 17 06/02/2023 20 Week of July 17-21, 2023: Date: Total Cases Signed Out: 07/17/2023 21 07/18/2023 48 07/19/2023 18 07/20/2023 7 07/21/2023 18 Note: Refer to master list attached for individual patient/case information. 5. In an interview on 12/06/2023 at 1620 hours in the laboratory's conference room, the facility's Histology Supervisor (as indicated on submitted Survey Entrance/Exit documents) confirmed the findings.
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 review of the CMS Report 209 Laboratory Personnel Report, electronic mail submission and staff interview, the laboratory director failed to provide overall management and direction of the laboratory services. (See D6020, D6028 and D6029)
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions for use, review of reagent logs, quality control records and interview of facility personnel, the laboratory director failed to establish and maintain the quality control program for Bacteriology and Hematology. (See D5449, D5543 and D5547)

D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based upon review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found two of five individuals identified as technical consultants failed to have documentation to meet the minimum education requirements. (See D6035)
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: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that two of forty four testing personnel failed to have documentation available to ensure they met minimum education requirements for performing moderate complexity testing. (See D 6065)
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 upon review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found two of five individuals identified as technical consultants failed to have documentation to meet the minimum education requirements. (See D6035)
D6035	TECHNICAL CONSULTANT QUALIFICATIONS

	CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based upon review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found two of five individuals identified as technical consultants failed to have documentation to meet the minimum education requirements. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found 5 personnel listed as Technical Consultants. Technical Consultant four was defined as Technical Consultant for Bacteriology, Mycology, Parasitology and Virology. Technical Consultant five was defined as the Technical Consultant for Chemistry (blood gasses). 2. Review of personnel files found: Technical Consultant four held an Associate of Applied Science degree in Medical Laboratory Technology. Technical Consultant five held an Associate of Applied Science in Respiratory Care Technology. 3. During interview of the administrative laboratory director conducted December 5, 2023 at 2:17 PM, he confirmed that personnel defined as technical consultants 4 and 5 had not earned at least a bachelor degree in a chemical, physical or biological science or medical technology.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

	The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that two of forty four testing personnel failed to have documentation available to ensure they met minimum education requirements for performing moderate complexity testing. (See D 6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that two of forty four testing personnel failed to have documentation available to ensure they met minimum education requirements for performing moderate complexity testing. Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified forty four testing personnel performing moderately complex testing. 2. Review of personnel records found two of forty four testing personnel failed to have foreign education credentials evaluated for equivalency to education obtained in the United States. Testing person 11 (hired 11/14 /2022) was educated in the Philippines and had no documentation of course by course evaluation of foreign education available for review. Testing person 37 (hired 04/03 /2023) was educated in Mexico and had no documentation of course by course evaluation of foreign education available for review. 3. During interview of the administrative laboratory director conducted on December 5, 2023 at 4:18 PM, he confirmed that a course by course evaluation of education for testing person 11 was not available for review. During additional interview on December 6, 2023 at 1:56 PM, he confirmed that a course by course evaluation of education for testing person 37 was not available for review.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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, the Laboratory Personnel report 209, personnel records and interview of facility personnel, the Laboratory Director failed to ensure competency assessments were performed for four of four testing personnel performing High complexity testing in Histopathology and Cytology in 2022 and 2023. The findings included: 1. Review of the procedure GEN:11 COMPETENCY ASSESSMENT (signed by laboratory director 05/20/2023) found on page 1 "Annual Competency Assessment for non-waived testing must be evaluated for each test system the employee is performing and must include the following elements: 1. Director observation of routine patient test performance including patient identification and preparation; specimen collection, handling, processing and testing. 2. Monitoring the recording of test results including critical results. 3. Review of intermediate test results worksheets, quality control records, proficiency testing results & preventive maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of testing previously analyzed specimens, internal blind testing or external proficiency testing samples. 6. Evaluation of problem solving skills." 2. Review of the Laboratory Personnel Report 209 found the laboratory listed 10 personnel performing high complexity testing. Testing persons 3, 4, 5 and 6 were defined as testing personnel performing histopathology and Cytology procedures. 3. Review of personnel files found no documentation of competency assessment evaluations for testing persons 3, 4, 5, and 6. 3. During interview of the laboratory director conducted December 5, 2023 at 4:18 PM, he confirmed that the did not perform competency assessments of the four personnel performing Histopathology and cytology procedures.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established and reassessed at least once every six months for five of five testing personnel performing cytology slide interpretations in 2023. See D5633 and D5637.