Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1009936	05/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Houston Fertility Institute	18220 Sh 249 Suite 300, Houston, 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 inspection, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the CMS 209 form, personnel records, the laboratory's AAB (American Association of Bioanalysts) proficiency testing results, and staff interview, it was revealed that the laboratory failed to ensure that proficiency testing samples were analyzed by personnel who routinely performed patient testing in the laboratory for ten of ten proficiency testing events in 2021 and 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Management' revealed the following: "Proficiency Testing - All testing personnel within the laboratory, as well as applicable personnel other department(s) shall be included in the pool of personnel required to complete the testing on Proficiency specimens. Personnel shall complete testing on Proficiency specimens on a rotating basis as staffing allows." 2. A review of the laboratory's CMS 209 form revealed 4 testing personnel performing moderate complexity testing. 3. A review of the laboratory's personnel records revealed 2 of 4 testing personnel were hired prior to 2021: Testing person #2 Hire date: 3/2019 Testing person #3 Hire date: 8/2014 4. A review of the laboratory's AAB proficiency testing records from 2021 and 2022 revealed the laboratory participated in the following 10 testing events: - Chemistry Q2 2021 - Comprehensive Chemistry (second event) - Chemistry Q2 2021 - Fertility Endocrinology (second event) - Chemistry Q3 2021 - Comprehensive Chemistry

	(third event) - Chemistry Q3 2021 - Fertility Endocrinology (third event) - Chemistry Q1 2022 - Comprehensive Chemistry (first event) - Chemistry Q1 2022 - Fertility Endocrinology (first event) - Chemistry Q2 2022 - Comprehensive Chemistry (second event) - Chemistry Q2 2022 - Fertility Endocrinology (second event) - Chemistry Q3 2022 - Comprehensive Chemistry (third event) - Chemistry Q3 2022 - Fertility Endocrinology (third event) 5. Further review of the proficiency testing events from 2021 and 2022 revealed all 10 events were tested by Testing person #3. 6. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24 /23 at 5:10 p.m. in the patient lounge, after review of the records, confirmed the above findings.
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 a review of the laboratory's policies, the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2022, and staff interview, it was revealed that the laboratory failed to have documentation of reviewing and evaluating the proficiency testing results for two of eight events in 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Management' revealed the following: "Investigation of Results When AAB send back the test results, check if the testing results are within acceptable range. If all results are within acceptable range, have the lab director review the results, sign and date the reports and then file the report in the PT files. If any result is out of acceptable range, contact lab director and an evaluation must be performed." 2. A review of the laboratory's AAB proficiency testing records from 2022 revealed the laboratory failed to have documentation of reviewing and evaluating the proficiency testing results for the following 2 events: - Embryology, Andrology & Fetal S2 2022 (second event) - Chemistry Q3 2022 Fertility Endocrinology (second event) 3. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24/23 at 5:10 p.m. in the patient lounge, after review of the records, confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2021 and 2022, and staff interview, it was revealed that the laboratory failed to have documentation of verifying the accuracy of analytes that were 'not graded' by the proficiency testing program for two of four proficiency testing events in 2021 and 2022. Findings include: 1. A review of the laboratory's American Association of Bionanlysts proficiency testing results from 2021 and 2022 revealed the following analytes were scored as 'not graded' and had a '?' next to the reported value: Embryology, Andrology & Fetal S2 2021 (second event) - Sperm

	Mobility Sample #2 Reported value: 44 Acceptable range: 16 - 40 Embryology, Andrology & Fetal S1 2022 (first event) - Sperm Cell ID sample #3 Reported value: Normal Acceptable response: Abnormal head AAB defines that "? = This score may not truly evaluate performance for this specimen which was not graded because of lack of participant consensus. You need to review this result to make sure that you can defend your response as accurate. Generally, if your result is within the given acceptable range, at minimum a documented QA/QC review is required. If you are outside the given acceptable range, you either need to justify why this range is not appropriate or treat this as a miss requiring corrective action" 2. Further review of the laboratory's proficiency testing records revealed the laboratory failed to have documentation of verifying the accuracy of the analytes that were scored as 'not graded'. 3. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24/23 at 5:10 p.m. in the patient lounge, after review of the records, confirmed the above findings.
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, quality control records for September 2022 to February 2023 and staff interview, the laboratory failed to follow its own policy and document monthly Technical Consultant quality control review for 3 of 6 months reviewed. Findings included: 1. Review of laboratory's policy "Quality Assurance for Laboratory" (effective 02/04) revealed: Page 3: "The Technical Consultant or Laboratory Supervisor shall review the quality control records monthly." And, Page 4: "Quality Control test records shall be reviewed each month by the Technical Consultant or Laboratory Supervisor." 2. Review of laboratory's quality control records for September 2022 to February 2023 revealed the following 3 of 6 reviewed months did not have documentation of Technical Consultant's quality control records' review: October 2022 November 2022 December 2022 3. In an interview on 05/24/2023 at 1215 hours in the patient's lounge, the laboratory's Technical Consultant (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Legend: CMS - Centers for Medicare and Medicaid
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 review of the COBAS e410 chemistry analyzer Operator's Manual, random patient sample COBAS test printouts for flagged results, patient's final reports, laboratory's policies and staff interview, the laboratory failed to follow manufacturer's

	instructions for 6 of 6 results with "Carryover" flags. Findings included: 1. Review of the COBAS e410 chemistry analyzer Operator's Manual (Version 2.1, document number 757-01-0311, page D-39) revealed: "11 Data Alarms ... CarOvr (carryover) Alarm Potential microparticle carry over Description The signal level of this sample is low. Cause Carryover from previous sample may have occurred. Remedy Rerun the sample Exception: Do not rerun the sample if either qualitative assays are negative or quantitative assays are below the lower limit of the clinical decision." 2. Review of random patient sample COBAS test printouts for flagged results and corresponding patient's final reports from January 4 to January 10, 2023, revealed the following 6 of 6 samples with CarOvr flags did not have documentation of the sample being rerun: Sample: 1897592 Date tested: 01/04/2023 Analyte: HCG BETA Instrument result: 0.115 mIU/ml (milli-international units per milliliter) Final report: 0.115 mIU/ml Sample: 1895441 Date tested: 01/05/2023 Analyte: LH Instrument result: 0.798 mIU /ml Final report: 0.798 mIU/ml Sample: 1900805 Date tested: 01/05/2023 Analyte: HCG BETA Instrument result: 0.405 mIU/ml Final report: 0.405 mIU/ml Sample: 1900910 Date tested: 01/06/2023 Analyte: LH Instrument result: 0.872 mIU/ml Final report: 0.872 mIU/ml Sample:1903719 Date tested: 01//9/2023 Analyte: HCG BETA Instrument result: 0.197 mIU/ml Final report: 0.197 mIU/ml Sample: 1902087 Date tested: 01/09/2023 Analyte: LH Instrument result: 1.10 mIU/ml Final report: 1.10 mIU /ml Sample: 1901407 Date tested: 01/10/2023 Analyte: LH Instrument result: 0.644 mIU/ml Final report: 0.644 mIU/ml 3. The laboratory was asked to provide documentation for rerunning the above CarOvr flagged specimens, and no such documentation was available for review prior to survey exit. 4. Review of laboratory's policies/procedures revealed CarOvr flags were not address. 5. In an interview on 05 /24/2023 at 1655 hours in the patient's lounge, the laboratory's Technical Consultant (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Legend: CMS - Centers for Medicare and Medicaid
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 a review of the Lab Temperature Quality Control logs, patient records, and staff interview, it was revealed that the laboratory failed to ensure the laboratory's humidity readings were within the laboratory's acceptable range for eight of twenty nine days reviewed from September 2022 to December 2022. Findings include: 1. A review of the Lab Temperature Quality Control logs revealed the following requirements: "Room temperature should be between 18 - 28C, humidity 20 - 50%, and refrigerator between 2 - 8C." 2. Further review of the Lab Temperature Quality Control logs from September 2022 to December 2022 revealed the following 8 days when the humidity readings were outside of the laboratory's acceptable range: 9/12/22 Humidity reading: 52% 9/19/22 Humidity reading: 51% 9/26/22 Humidity reading: 52% 10/17/22 Humidity reading: 51% 11/7/22 Humidity reading: 53% 11/8/22 Humidity reading: 52% 12/6/22 Humidity reading: 54% 12/13/22 Humidity reading:

	52% 3. A review of patient records revealed the following patient's specimens were resulted on the days when the humidity was outside of the laboratory's acceptable range: 9/12/22 Patients: 684824, 684676, 684475, 685949, 687300 9/19/22 Patients: 688519, 679852, 115927, 689314 9/26/22 Patients: 677756, 683889, 688470, 687242, 173247, 689990 10/17/22 Patients: 689446, 685794, 688921, 688404, 688590, 689792, 690698 11/7/22 Patients: 678452, 690795 11/8/22 Patients: 178918, 692282 12/6/22 Patients: 99607, 689206 12/13/22 Patients: 692460, 139938, 677456, 192538 4. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5 /24/23 at 5:10 p.m. in the patient lounge, after review of the records, confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: A. Based on surveyor's observations in the laboratory, review of manufacturer instructions for use and staff interview, the laboratory failed to document amended expiration dates on two of two reconstituted COBAS controls stored in the refrigerator (at 2-8C). Findings included: 1. Surveyors observations in the laboratory on 05/24 /2023 at 1120 hours revealed two vials of reconstituted PreciControl Universal COBAS endocrinology controls stored in the refrigerator, labeled with preparation date of 04/26 (no year) and expiration date of the lyophilized product (prior to reconstitution). There was no documentation of amended expiration date on the vials, or the date controls were placed in use. These were: Control 1: PC U1 Lot: 55640390 Exppiration date (lyophilized): 2023-08-31 Control 2: PC U2 Lot: 55640590 Exppiration date (lyophilized): 2023-08-31 2. Review of manufacturer instructions for use for the PreciControl Universal COBAS endocrinology controls (REF 11731416160, 2023-05, V 13.0) revealed: "Stability of all the components - except for insulin - in the reconstituted control serum: ... or at 2-8 C 3 days" 3. In an interview on 05/24/2023 at 1125 hours in the laboratory, the facility's Technical Consultant (as indicated on submitted form CMS 209), after review of the vials, confirmed the findings. B. Based on surveyor's observations in the laboratory, review of manufacturer instructions for use and staff interview, the laboratory failed to follow manufacturer instructions for storage for two of two reconstituted COBAS calibrators stored in the refrigerator (at 2-8C). Findings included: 1. Surveyors observations in the laboratory on 05/24/2023 at 1120 hours revealed the following 2 calibrators stored in the refrigerator, labeled with preparation date of 05/16 (no year) and an expiration date of the lyophilizied product (prior to reconstitution). These were: CalSet II FSH Lot: 57782902 Exppiration date (lyophilized): 2023-12-31 CalSet II LH Lot: 59922402 Exppiration date (lyophilized): 2023-06-30 2. Review of the manufacturer instructions for use (IFU) for the COBAS LH CalSet II (REF 03561097190, 2023-05, V14.0) and the FSH Cal Set II (REF 0893417190, 2022-10, V2.0) revealed both IFUs stated: "Stability of reconstituted calibrators: at -20 C (5 C) 3 months (freeze only once) on the analyzer at 20-25 C use only once" 3. In an interview on 05/24/2023 at 1125 hours in the laboratory, the facility's Technical Consultant (as indicated on submitted form CMS 209), after review of the vials and the IFUs, confirmed the

	findings. Legend: C - Degrees Celsius LH - Luteinizing hormone FSH - Follicle stimulating hormone CMS - Centers for Medicare and Medicaid
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 COBAS e410 chemistry analyzer Operator's Manual, review of laboratory's policies, laboratory's instrument maintenance records from October 2022 to February 2023 and staff interview, the laboratory failed to document maintenance for 8 instances it was required within the reviewed 5-month period. Findings included: 1. Review of the COBAS e410 chemistry analyzer Operator's Manual (Version 2.1, document number 757-01-0311, page C-11) revealed: "It is important that you keep to the recommended schedule for all maintenance actions." And, "Weekly Maintenance Task Clean the sipper probe Clean the incubator and aspiration station Table C-2 Maintenance schedule: Weekly" And, "Every two weeks Maintenance Task Clean the rinse station Liquid flow cleaning Table C-3 Maintenance schedule: Every two weeks" 2. Review of laboratory's policy "Quality Assurance for Laboratory" (effective 02/04, page 5) revealed: "Scheduled and Preventive Maintenance shall be performed in accordance with the manufacturer's recommendations." 3. Review of the COBAS e410 instrument's maintenance records from October 2022 to February 2023 revealed no documentation of maintenance for the following 8 instances it was required within the reviewed 5-month period: No documentation of Weekly Maintenance the week of: 11/28/2022 to 12/02/2022 12/19 /2022 to 12/23/2022 No documentation of Every Two Weeks Maintenance the week of: 10/24/2022 to 10/28/2022 11/14/2022 to 11/18/2022 12/05/2022 to 12/09/2022 12 /19/2022 to 12/23/2022 01/16/2023 to 01/20/2023 02/20/2023 to 02/24/2023 4. In an interview on 05/24/2023 at 1210 hours in the patient's lounge, the laboratory's Technical Consultant (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Legend: CMS - Centers for Medicare and Medicaid
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: I. Based on a review of the laboratory's policies, the laboratory's maintenance records for 2022, and staff interview, it was revealed that the laboratory failed to have documentation of performing the following maintenance procedures: a) daily cleaning of the Lab- Line slide warmer for 29 of 29 days from September 2022 to December

	2022 b) monthly scratch checks on the two Makler counter chambers for twelve of twelve months in 2022 c) annual centrifuge cleaning and calibration for the Centra CL2 centrifuge for 2022 d) annual pipette calibrations for the two Eppendorf pipettes for 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Control' revealed the following: "QC of equipments in Andrology laboratory Daily - Slide Warmer Slide warmer should also be cleaned with Multi-clean before and after each use. Monthly - Makler counter chambers Makler counter chamber are checked monthly to ensure that there are no scratches, which could possibly interfere with the counting of sperm. Bi-annually or Annually - Centrifuge cleaning and calibration Centrifuge is checked annually using the tachometer. During calibration, the centrifuge must be cleaned with 1% 7X, or if there is a spill of sample or dirty on the surface, clean with 1% 7X. This must be documented on paper or calibration form." 2. A review of the laboratory's policy titled 'Pipette Calibration' revealed the following: "Calibrate the pipette once a year in each laboratory and keep the record for future inspection and evaluation." 3. A review of the laboratory's maintenance records for 2022 revealed the laboratory failed to have documentation of performing the following maintenance procedures: a) daily cleaning of the Lab- Line slide warmer (model number: 29095) for the following 29 days from September 2022 to December 2022: 9/6/22, 9/12/22, 9/13/22, 9/19/22, 9/20/22, 9/26/22, 9/27/22, 10/3/22, 10/4/22, 10/10/22, 10/11/22, 10/17/22, 10/18/22, 10/24/22, 10/25/22, 10/31/22, 11/1/22, 11/7 /22, 11/8/22, 11/14/22, 11/15/22, 11/28/22, 11/29/22, 12/5/22, 12/6/22, 12/12/22, 12 /13/22, 12/19/22, 12/20/22 b) monthly scratch checks on the two Makler counter chambers for twelve of twelve months from January 2022 to December 2022 c) annual centrifuge cleaning and calibration for the Centra CL2 centrifuge (serial number: H65014) for 2022 d) annual pipette calibrations for the two Eppendorf pipettes (20 ml serial number: 22194A and 100 ml serial number: 2150691) for 2022. 4. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5 /24/23 at 5:15 p.m. in the patient lounge, after review of the records, confirmed the above findings. II. Based on surveyor observation, a review of the Olympus BX41 Instruction Manual, the laboratory's records, and staff interview, it was revealed that the laboratory failed to define the frequency and document maintenance procedures for one of one Olympus BX41 microscope used for semen analysis testing. Findings include: 1. Surveyor observation of the laboratory on 5/24/23 at 3:30 p.m. revealed the laboratory used an Olympus BX41 microscope (serial number: H65019) for patient semen analysis testing. 2. A review of the Olympus BX41 Instruction Manual revealed the following: "Maintenance and Storage - Clean all glass components by wiping gently with gauze." 3. A review of the laboratory's records revealed the laboratory failed to define the frequency and document the cleaning of the Olympus BX41 microscope. 4. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24/23 at 5:10 p.m. in the patient lounge, after review of the records, confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for the Accu-Beads quality control material, a random review of the QC Bead Count for QC forms, patient test

	records, and staff interview, it was revealed that the laboratory failed to ensure the duplicate bead counts for each level of control were within 10% of each other prior to testing patients for fourteen of twenty days reviewed between September 2022 and February 2023. Findings include: 1. A review of the manufacturer's instructions for the Accu-Beads quality control (QC) material (Doc. # M-75-02-44 Rev. A) revealed the following steps for performing quality control testing: "- Count the beads according to a standard counting procedure. - When using a fixed chamber with a gridded coverslip or a gridded slide, follow the chamber manufacturer's counting instructions. - Calculate the bead concentration according to the chamber manufacturer's instructions. - Count another aliquot of the same sample. The results should be within 10% of each other to be considered valid. - If the results are valid, average the two counts and compare to the accu-beads acceptable concentration. - The counting procedure above should be performed with all accu-beads concentrations." 2. A random review of the QC Bead Count for QC forms and patient test records from September 2022 to February 2023 revealed the following 14 days when the duplicate bead counts for the QC material were not within 10% of each other and patient's samples were reported: Date: 9/12/22 High QC counts: 53 and 62 Percent difference: 15% Patients reported: 684824, 684676, 684475, 685949, 687300 Date: 9/19/22 Low QC counts: 26 and 30 Percent difference: 14% Patients reported: 688519, 679852, 115927, 689314 Date: 10/11/22 Low QC counts: 25 and 30 Percent difference: 18% Patients reported: 686366, 689378, 690430, 139938, 686831 Date: 10/18/22 Low QC counts: 26 and 32 Percent difference: 20% Patients reported: 210338, 683889, 689989, 681345, 690369 Date: 11/7/22 Low QC counts: 30 and 34 Percent difference: 12% Patients reported: 678452, 690795 Date: 11/14/22 Low QC counts: 26 and 33 Percent difference: 23% High QC counts: 59 and 67 Percent difference: 12% Patients reported: 691613, 692366, 690698 Date: 11/28/22 Low QC counts: 26 and 30 Percent difference: 14% Patients reported: 692450 Date: 12/5/22 Low QC counts: 26 and 33 Percent difference: 23% Patients reported: 691966, 691499, 189858 Date: 12/20/22 Low QC counts: 28 and 34 Percent difference: 19% Patients reported: 99607, 689206 Date: 1/3/23 High QC counts: 59 and 66 Percent difference: 11% Patients reported: 6692465, 677381 Date: 1/24/23 High QC counts: 59 and 67 Percent difference: 12% Patients reported: 175460 Date: 2/14/23 Low QC counts: 28 and 34 Percent difference: 19% High QC counts: 57 and 66 Percent difference: 14% Patients reported: 695397, 694715, 695755 Date: 2/24/23 Low QC counts: 28 and 34 Percent difference: 19% Patients reported: 685560, 697001, 696566 Date: 2/27/23 High QC counts: 56 and 67 Percent difference: 17% Patients reported: 696745, 693358 3. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24 /23 at 5:10 p.m. in the patient lounge, after review of the records, confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records from January 2022 to December 2022, and staff interview, it was revealed that the laboratory failed

	to have documentation of performing twelve of twelve monthly quality assurance reviews, four of four quarterly quality assurance reviews, and one of one annual quality assurance review as required in 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Management Plan' revealed the following: "Perform all monthly quality management activities listed on the review schedule. Use the Quality Management Monthly Review to record all findings. a) Monthly activities: - Review Specimen/Requisition Problem Log - Review Problems Encountered Log - Review of past and current Problems Encountered Logs - Review procedure change requests - Review lot numbers and control ranges to verify that correct insert is followed. Compare records of QC flags to instrument problems, patient values & PT results - Review intra-laboratory comparison reports - Review of function check records, including temperature, humidity, etc. - Review of maintenance records - Review of critical value and phone log - Review of E/P/C Log for appropriate entries - Review agenda and staff signoff for monthly meetings b) Perform all quarterly quality assurance activities listed on the review schedule. Use the Quality Management Quarterly Review form to record audit findings. Quarterly activities: - Review personnel files - Perform a chemical inventory & compare to MSDS file - Review representative sample of requisitions - Perform correlation studies at defined interval - Perform audit of representative number of test reports generated during review period - Review Error/Problem/Complaint logs for appropriate entries - Audit representative number of reports for review period c) Perform all annual quality management activities listed on the review schedule. Use the Annual Quality Management Assessment form to document completion of annual assessment. Annual activities: - Review all PT documentation received within review period - Check for review signatures and date for each procedure - Review personnel files - Review of Bloodborne Pathogens and Exposure Control Plan annually" 2. A review of the laboratory's records from January 2022 to December 2022 revealed the laboratory failed to have documentation of performing the twelve monthly reviews (documented on the Quality Management Monthly Review form), the four quarterly reviews (documented on the Quality Management Quarterly Review form), and the annual quality assurance review (documented on the Annual Quality Management Assessment form) as required in 2022. 3. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24/23 at 5:25 p.m. in the patient lounge, after review of the records, confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's submitted CMS 209 form, personnel files, and staff interview, it was revealed that the technical consultant failed to perform competency assessments on two of four testing personnel in 2021 and two of four testing personnel in 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance for Laboratory' revealed the following: "Employee competency shall be evaluated before testing patient specimens. Competency re-assessment shall be performed annually for all employees." 2. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 4 testing personnel performing moderate complexity testing. 3. A review of the

	laboratory's personnel records revealed no documentation of the technical consultant performing a competency assessment for the following: - Testing person #2 in 2021 - Testing person #3 in 2021 - Testing person #2 in 2022 - Testing person #3 in 2022 4. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5 /24/23 at 10:30 a.m. in the patient lounge, after review of the records, confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that two of four testing personnel failed to have documentation of training prior to performing patient testing on the Roche Cobas e411 analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 4 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that testing person #2 and testing person #4 failed to have documentation of training on the Roche Cobas e411 analyzer. 3. An interview with the technical supervisor (as indicated on the CMS 209 form) on 5/24/23 at 10:30 a.m. in the patient lounge, after review of the records, confirmed the above findings.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing results and staff interview, it was revealed that the laboratory director failed to ensure all proficiency testing results were reviewed. (Refer to D5211)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 quality assurance records and staff interview, it was revealed that the laboratory director failed to ensure quality assurance programs maintained the quality of laboratory services provided and identified failures in quality as they occur. (Refer to D5793)