Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0052671	01/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hamilton Hospital Laboratory	901 W Hamilton Po Box 158, Olney, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable CLIA Conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted test menu, review of laboratory's test records for 2022 , review of the laboratory's twice annual accuracy verification records for 2021 and 2022and staff interview, it was determined the laboratory failed to document twice annual accuracy verification for Cotinine Screen 1 of 10 toxicology analytes tested by the laboratory. Findings included: 1. Review of the laboratory's submitted test menu revealed the laboratory performed screen for Cotinine, 1 of 10 toxicology analytes tested by the laboratory. 2. Review of laboratory's test records for 2022 revealed the laboratory performed 114 Cotinine screens in 2022. 3. Review of the laboratory's twice annual accuracy verification records for 2021 and 2022 revealed the laboratory did not have documentation of performing twice annual accuracy verification for Cotinine screen. 4. The laboratory was asked to provide

	documentation of performing twice annual accuracy verification for Cotinine screen and no such documentation was available for review prior to survey exit. 5. In an interview on 01/26/2023 at 1100 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted test menu, review of manufacturer's package insert for the Profile MedTox Urine Drug Screen, review of laboratory's test records for 2022, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to have protocols in place to verify un-adulteration of urine samples prior to testing. Findings included: 1. Review of the laboratory's submitted test menu revealed the laboratory performed Urine Drug Screen testing using the PROFILE -V MEDTOX Scan Drugs of Abuse Test System. 2. Review of the PROFILE -V MEDTOX Scan Drugs of Abuse Test System package insert revealed: "The PROFILE -V MEDTOX Scan Drugs of Abuse Test System is only for use with unadulterated preservative free, human urine samples. Urine samples that are either extremely acidic (below pH 4.0) or basic (above pH 9.0) may produce erroneous results. If adulteration is suspected, obtain an additional specimen and re-test." 3. Review of laboratory's test records revealed there was no documentation of samples' verification of un-adulteration. The laboratory performed 578 urine drug screens in 2022. 4. Review of laboratory's policies an procedures revealed the laboratory did not have protocols in place to verify un-adulteration of urine samples prior to testing. 5. In an interview on 01/26/2023 at 1220 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
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 manufacturer instructions for use for the Beckman Coulter Access Hybritech PSA (prostate specific antigen), random review of patient records from December of 2022 to January of 2023, review of laboratory's PSA test volumes for 2022 and staff interview, it was determined the laboratory failed to follow manufacturer indications for patient age for 2 of 20 patients whose records were reviewed. Findings included: 1. Review of the manufacturer instructions for use for the Beckman Coulter Access Hybritech PSA (document A85076 P) revealed: "INTENDED USE ... This device is indicated for measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in detection of prostate cancer in men aged 50 years or older." And, "This device is further indicated for the serial measurement of PSA to aid in prognosis and management of patients with prostate cancer." 2. Random review of patient records from December of 2022 to January of 2023 revealed the following 2 of 20 patients' samples were tested outside of the age requirements, without diagnosis of prostate cancer: Patient number : 00638284 Age: 41 Tested: 01/23/2023 PSA result: 0.36 ng/mL (nanograms per milliliter) Diagnosis: Dysuria Patient number: 00637845 Age: 44 Tested: 01/18/2023 PSA result: 0.80 ng/mL Diagnosis: Testicular Hypofunction 3. Review of laboratory's test volumes revealed the laboratory performed 449 PSA tests in 2022. 3. In an interview on 01/25/2023 at 1610 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
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 laboratory's maintenance records for the Beckton Dickinson (BD) BACTEC FX40 blood culture system for 2022, review of manufacturer's operator's manual for the said system, review of the laboratory's annual test volumes and staff interview, it was determined the laboratory failed to document 8 of 8 reviewed monthly maintenance of air filter cleaning as per manufacturer requirements. Findings included: 1. Review of the laboratory's maintenance records for the BD BACTEC FX40 blood culture system for 2022 revealed no documentation of monthly air filter cleaning for the following 8 of 8 months reviewed: January 2022 February 2022 March 2022 April 2022 May 2022 October 2022 November 2022 December 2022 2. Review of manufacturer's operator's manual for the BD BACTEC FX40 blood culture system (document: 8090414) revealed: "Cleaning Air Filters ... These filters must remain clean and unobstructed; restricted airflow from dirty filters may cause the instrument interior to reach excessive temperatures, which can affect results and possibly cause hardware malfunctions or failures." 3. Review of the laboratory's test volumes revealed the laboratory performed 193 blood cultures in 2022. 4. In an interview on 01/27/2023 at 1050 hours in the chapel/conference room,

	the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of laboratory's Prothrombin Calibration Worksheets with function check records for its coagulation centrifuge for 2021 and 2022, review of laboratory's policies and procedures, review of the laboratory's annual test volumes and staff interview, it was determined the laboratory failed to define a function check protocol and defined frequency for verification of centrifuge's ability to produce platelet poor plasma. Findings included: 1. Review of laboratory's Prothrombin Calibration Worksheets with function check records for its coagulation centrifuge for 2021 and 2022 revealed the laboratory performed verification of centrifuge's ability to produce platelet poor plasma as follows: 05/10/2021 02/22/2022 2. Review of laboratory's policies and procedures revealed the laboratory did not have function check protocols and defined frequency for verification of centrifuge's ability to produce platelet poor plasma. 3. Review of the laboratory's test volumes revealed the laboratory performed coagulation tests on 533 patient samples in 2022. 4. In an interview on 01/26/2023 at 1340 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), stated that verification of centrifuge's ability to produce platelet poor plasma should be performed every 6 months, but could not provide a policy/procedure for the process. This confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 laboratory's quality control (QC), calibration and calibration verification records for 2021 and 2022, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to document calibration verification at least every 6 months for 4 of 4 analytes requiring calibration verification. Findings included: 1. Review of laboratory's QC and calibration records for 2021 and 2022 revealed the following analytes requiring 6 months calibration verification: Salicylate Number of calibrators: 2 Controls: 2 Total Bilirubin Number of calibrators: 1 Controls: 2 Direct Bilirubin Number of calibrators: 1 Controls: 2 BNP (B-Type Natriuretic Peptide) Number of calibrators: 2 Controls: 2 2. Review of laboratory's calibration verification records for 2021 and 2022 revealed the following calibration verifications exceeded the 6 months calibration verification requirement: Analyte: Salicylate Calibration verification date: 05/03/2022 Next calibration verification: 12/14/2022 Time elapsed: 7 months, 9 days Analyte: Total Bilirubin Calibration verification date: 05/05/2022 Next calibration verification: 12/20/2022 Time elapsed: 7 months, 15 days Analyte: Direct Bilirubin Calibration verification date: 05/05/2022 Next calibration verification: 12/20/2022 Time elapsed: 7 months, 15 days Analyte: BNP Calibration verification date: 04/08/2021 Next calibration verification: 12/22/2021 Time elapsed: 8 months, 14 days 3. Review of laboratory's policies and procedures revealed there were no protocols in place for frequency and performance of calibration verification. 4. In an interview on 01/25/2023 at 1550 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quiagen Individualized Qualiy Contol Plan (IQCP) Template for the QiA-Stat Respiratory Panel, review of manufacturer's package insert for the QIAstat-Dx RP Control Panel M360, review of the laboratory's quality control (QC) records for the QIAstat-DX Respiratory Panel for January to June and October to December of 2022, review of laboratory's IQCP establishment studies for the QiA-Stat Respiratory Panel, review of the laboratory's annual test volumes and staff interview, it was determined the laboratory failed to document performance of two control materials (positive/negative) with each molecular amplification procedure, or have an IQCP in place that justified once a new lot/shipment QC. Findings included:

	1. Review of the Quiagen Individualized Qualiy Contol Plan Template for the QiA-Stat Respiratory Panel revealed: "Ultimately it is the responsibility of the lab director to determine the appropriate IQCP for your laboratory." And, "Note: This should comply with your state and federal guidelines." 2. Review of manufacturer's package insert for the QIAstat-Dx RP Control Panel M360 (document: M360 09JULY2019. 00) revealed: "Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs." 3. Review of the laboratory's QC records for the QIAstat-DX Respiratory Panel for January to June and October to December of 2022 revealed the laboratory performed QC once each new lot/shipment as follows: New Lot: 169048053 Expiration: 06/05/2022 Tested: 01/07/2022 New Lot: 172010555 Expiration: 07/11/2022 Tested: 04/20/2022 New Shipment: Lot 172010555 Expiration: 07/11/2022 Tested: 06/17/2022 New Lot: 172034014 Expiration: 03/16 /2023 Tested: 10/12/2022 New Lot: 220200 Expiration: 04/21/2023 Tested: 11/11 /2022 4. Review of laboratory's IQCP establishment studies for the QiA-Stat Respiratory Panel (signed into effect on 04/14/2020) revealed the laboratory's IQCP failed to verify performance of two control materials (positive/negative) each day for the interval of a lot's expiration in order to confirm that the lot's QC will not vary in acceptability over time, for each module of the test system. The QC for the establishment of IQCP was performed as follows: Analytic Module Serial Number : 10419021 Date: Positive A Positive B Negative 02/18/2020 Tested Not tested Tested 02/19/2020 Not tested Tested Tested 02/20/2020 Not tested Tested Not tested 02/25 /2020 Not tested Tested Tested 02/26/2020 Tested Tested (failed) Not tested 02/27 /2020 Tested Tested Not tested 02/28/2020 Not tested Tested Tested 03/16/2020 Not tested Not tested Tested Analytic Module Serial Number :10419022 Date: Positive A Positive B Negative 02/18/2020 Not tested Tested Not tested 02/19/2020 Tested Tested Not tested 02/20/2020 Tested Not tested Tested 02/25/2020 Not tested Tested Not tested 02/26/2020 Tested Not tested Not tested 02/27/2020 Not tested Not tested Tested 03/16/2020 Not tested Not tested Tested 03/17/2020 Tested Not tested Not tested The interval tested did not support the IQCP's assumption that control acceptability extends through the expiration date of the lot, and that QC testing can only be performed once each new lot number/shipment. 5. Review of the laboratory's test volumes revealed the laboratory performed QiA-Stat Respiratory Panel testing on 235 patient samples in 2022. 6. In an interview on 01/27/2023 at 1400 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, review of laboratory's quality control (QC) records for the Beckman Coulter DxH hematology analyzer for September to December of 2022, review of patient records for the same interval and staff interview, it was determined the laboratory failed to document acceptable levels

	of controls at least once a day patient samples were assayed for 3 of 122 days reviewed. Findings included: 1. Review of laboratory's "Quality Control Policy and Procedure" (Policy number Q1, last revised 10/04/2016) revealed: "Operation Rules: All quality control material shall be run and evaluated prior to releasing patients results." And, "QC Outliers: Samples out of testing limits must be repeated for verification." 2. Review of laboratory's QC for the Beckman Coulter DxH hematology analyzer for September to December of 2022 revealed the following QC failures /omissions: Control Type: COULTER LATRON CP-X Lot number: 103156680 Expiration Date:01/15/2023 09/24/2022 at 06:17:31 Control Failures: D (AL2): 253.50 RH D (MALS): 253.50 RH D(UMALS): 253:50 RH No repeat testing /corrective action was documented on 09/24/2022 for this control. Next tested: 09/26 /2022 at 06:35:47 09/25/2022 - No QC was documented for COULTER LATRON CP-X control 10/20/2022 at 06:56:52 Control Failures: D %CV (C): 15.00 H D (LALS): 3.00 L D %CV (LALS): 25.44 H D (AL2): 2.00 L D %CV (AL2): 22.34 H No repeat testing/corrective action was documented on 10/20/2022 for this control. Next tested: 10/21/2022 at 06:44:45 3. Review of patient records for the dates QC failed/was omitted revealed the following patient samples were tested: 09/24/2922 Patients: 00626179 00626180 00626181 00626182 00626183 00625773 00626168 09/25/2022 Patients: 00626192 00626191 00626190 00626189 00626179 00626168 10/20/2022 Patients: 00629139 00629162 00628394 00629168 00628158 00629169 00629180 00629190 00629174 00629176 00629173 00629175 00629222 00629227 00629442 00629229 00629256 00629262 4. In an interview on 01/26/2023 at 1350 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, 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 manufacturer instructions for use for the Beckman Coulter MicroScan RENOK Rehydrator/Inoculator System, review of the laboratory's maintenance records for the RENOK inoculator for 2021 and 2022, review of laboratory's corrective action records and staff interview, it was determined the laboratory failed to document corrective action for 4 of 19 reviewed RENOK monthly maintenance, where tray weights/volumes were documented out of required range. Findings included: 1. Review of manufacturer instructions for use for the Beckman Coulter MicroScan RENOK Rehydrator/Inoculator System (Document 9020-7657, Rev. BB) revealed: "Checking the dispense volume Check the fill volume at least once per month, and whenever low fills are suspected." And, "Record the final (tray) weight to determine the appropriate inoculation volume. The proper weight of the inoculated cover tray should be within a 10.1 to 12.0 gram threshold." 2. Review of the laboratory's maintenance records for the Beckman Coulter MicroScan RENOK

	Rehydrator/Inoculator System for 2021 and 2022 revealed the following 4 of 19 reviewed RENOK monthly maintenance tray weights/volumes were documented as out of manufacturer required range: Date: Weight(grams): 06/01/2021 10.00 10/11 /2021 10.00 11/01/2021 10.00 05/09/2022 9.90 3. Review of laboratory's corrective action records for the MicroScan RENOK Rehydrator/Inoculator System revealed no documentation of corrective action for the above days the instrument's tray weight /volume was out of manufacturer defined range. 4. Laboratory was asked to provide documentation of corrective action for the above out of range tray weights/volumes and no such documentation was available for review prior to survey exit. 5. In an interview on 01/27/2023 at 1130 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records for the Beckman Coulter DxH hematology analyzer for September to December of 2022, review of laboratory's corrective action records for the same interval and staff interview, it was determined the laboratory failed to document corrective action for 2 of 2 failed QC instances. Findings included: 1. Review of laboratory's QC for the Beckman Coulter DxH hematology analyzer for September to December of 2022 revealed the following QC failures: Control Type: COULTER LATRON CP-X Lot number: 103156680 Expiration Date:01/15/2023 09/24/2022 at 06:17:31 Control Failures: D (AL2): 253.50 RH D (MALS): 253.50 RH D(UMALS): 253:50 RH No corrective action was documented on 09/24/2022 for this control. 10/20/2022 at 06:56:52 Control Failures: D %CV (C): 15.00 H D (LALS): 3.00 L D %CV (LALS): 25.44 H D (AL2): 2.00 L D %CV (AL2): 22.34 H No corrective action was documented for this control. 2. Review of laboratory's corrective action records for QC failures revealed no documentation of corrective action for the above 2 of 2 QC failure instances. 3. In an interview on 01/26/2023 at 1350 hours in the chapel/conference room, the laboratory's Technical Supervisor number 2 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory's quality assessment records, review of policies /procedures and manufacturer instructions, review of laboratory's maintenance, quality control, calibration/calibration verification and corrective action records and staff interview, it was determined the laboratory's quality assurance failed to identify and correct issues in the analytic systems of the laboratory. Refer to D5403, D5411, D5429, D5435, D5439, D5445, D5447, D5781 and D5783.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, review of patient test records and staff interview, it was determined the laboratory's TC failed to ensure laboratory's QC was maintained. Refer to D5447.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of laboratory's maintenance records, review of corrective/remedial action records, review of manufacturer's instructions and staff interview, it was determined the laboratory's Technical Consultant failed to ensure corrective actions are taken. Refer to D5781.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory's quality control records, review of corrective/remedial action records, review of patient test reports and staff interview, it was determined the laboratory's Technical Consultant failed to ensure corrective /remedial actions were taken prior to reporting patient results. Refer to D5783.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control 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 control (QC) records, review of the laboratory's Individualized Quality Control Plans (IQCP), review of patient test records and staff interview, it was determined the Laboratory Director failed to ensure QC was established and maintained. Refer to D5445 and D5447.
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 laboratory's quality assurance records and staff interview, it was determined the Laboratory Director failed to ensure laboratory's quality assurance identified and corrected issues with analytic systems. Refer to D5791.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's maintenance records, review of the laboratory's quality control records and staff interview, it was determined the Laboratory Director failed to ensure remedial actions were taken. Refer to D5781 and D5783.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control records, review of laboratory's remedial action records and staff interview, it was determined the Laboratory Director failed to ensure patient test results were reported only when the system is functioning properly. Refer to D5447.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of laboratory's Individualized Quality Control Plans' establishment studies and staff interview it was determined the laboratory's Technical Supervisor failed to ensure appropriate QC was established. Refer to D5445.