Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0675182	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Seymour Hospital Laboratory	200 Stadium Drive, Seymour, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records, analytic records, and interview with facility personnel, the laboratory director and the individual performing testing failed to attest to the routine integration of the samples into the patient workload for 1 of 3 Miscellaneous Chemistry events in 2017. The findings included: 1. Based on review of the attestation page for the 2nd Miscellaneous Chemistry event in 2017: "SIGNATURES REQUIRED - Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. either the attestation statement below or a printed copy of the form provided online can be used for this purpose." The attestation sheet was not signed by the testing personnel or the laboratory director. 2. Based on review of analytic records, Testing Person 9 (as listed on the CMS-209 laboratory personnel report) performed testing by the MedTox Scan toxicology method on the API samples on 10/30/2017. 3. In an interview at 12:50 hours on 8/28/2018 in the conference room, the Laboratory Manager confirmed the laboratory director and the testing person failed to sign the attestation to the routine integration of proficiency samples into the laboratory's workload using the laboratory's routine methods.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, competency assessment documentation, and interview with facility personnel, the laboratory failed to establish and follow written policies to assess employee and consultant competency to ensure 4 of 12 testing personnel competency assessments were performed by a qualified Technical Consultant in 2017 and 2018. The findings included: 1. Based on review of policies and procedures, the laboratory had established a written policy titled "ANNUAL PERSONNEL COMPETENCY ASSESSMENT", effective February 24, 2009. The policy states the following: "All Clinical Laboratory technologists are to be tested annually for competency in all areas of Clinical Laboratory. These include: Blood Banking, Chemistry, Coagulation, Hematology, Urinalysis, Microbiology, and Miscellaneous areas. Competency testing will include CAP proficiency testing or other CMS approved Proficiency Testing Program on rotation schedule for all technologist. Clinical Laboratory in-house examinations will be done annually, on their anniversary dates for all technologists. A passing grade of at least 70 percent must be achieved. When a technologist fails an examination in any area of the Clinical Laboratory, he/she will be retested in that area after in-service by supervisor. If a second failure occurs, the technologist will be placed on probation for 30 days with additional in-servicing and then retested. If a third failure occurs, the technologist will be suspended." The policy failed to address the following requirements as required in the CLIA regulations at subpart M of 42 CFR part 493: 493.1413 Standard; Technical consultant responsibilities. The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. (a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and (b) The technical consultant is responsible for - (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to - (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; (ii) Monitoring the recording and reporting of test results; (iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; (iv) Direct observation of performance of instrument maintenance and function checks; (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and (vi) Assessment of problem solving skills; and (9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. Refer to 493.1413(b)(8) and 493.1451(b)(8) for specific testing personnel competency requirements and refer to 493.1407(e)(12) and 493.1445(e)(13) for establishing policies to monitor each individual's competency and identify remedial training or continuing education needs. Documented competency assessment is required for the following named positions on the Form 209: technical

	consultant, clinical consultant, technical supervisor, general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must be performed at a frequency determined by the laboratory. If these people (TC, CC, TS, GS) perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities. 2. Based on review of competency assessment documentation for respiratory therapy staff that before routine chemistry blood gas testing, the laboratory failed to ensure the individual assessing competency was qualified as a Technical Consultant for the routine chemistry specialty. The competency assessment for Testing Person 11 (as listed on the CMS-209) was signed by Testing Person 8 on 01/03/2017 and 01/08/2018. The competency assessment for Testing Person 12 (as listed on the CMS-209) was signed by Testing Person 8 on 01 /03/2017 and 01/08/2018. The competency assessment for Testing Person 8 (as listed on the CMS-209) was signed by Testing Person 10 on 01/03/2017 and 01/08/2018. The competency assessment for Testing Person 10 (as listed on the CMS-209) was signed by Testing Person 8 on 01/03/2017 and 01/08/2018. Testing Person 8 and Testing Person 10 do not meet the CLIA requirements in subpart M for qualification as a Technical Consultant in moderate complexity routine chemistry. 3. In an interview at 11:22 hours on 8/28/2018 in the break room, the Laboratory Manager stated the laboratory had developed a competency assessment policy and stated that some of the requirements listed above were missing from the laboratory's procedure.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of policies and procedures, competency assessment documentation, and interview with facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236 for 2016 and 2017. The findings included; 1. Based on review of laboratory policies and procedures, competency assessment documentation, and interview with facility personnel, the laboratory failed to establish and follow written policies to assess employee and consultant competency to ensure 4 of 12 testing personnel competency assessments were performed by a qualified Technical Consultant. Refer to D5209. Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and other non-laboratory areas or departments of the facility of which it is a part. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must

	monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation. QA of the General Laboratory System includes assessing practices/issues related to: o Patient confidentiality; o Specimen identification and integrity; o Complaint investigations; o Communications; o Personnel competency; and o Proficiency testing performance. An example would be monitoring the type and number of complaints received by the laboratory such as a particular client continuously complaining about the laboratory's failure to promptly respond to STAT test requests. The laboratory must have documentation that the complaint was investigated and appropriate action taken to correct the problem. 2. In an interview at 10:34 hours on 8/30/2018 in the laboratory, the Laboratory Manager stated the laboratory had not developed a formal written quality assessment policy.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of policies and procedures and interview with facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242 for 2016 and 2017. The findings included; 1. The surveyor requested quality assessment documentation at 10:30 hours on 8/30/2018. Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the other non-laboratory areas or departments of the facility of which it is a part. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation. QA of the Preanalytic System includes assessing practices/issues related to test requests, specimen submission, handling and referral. Some examples include: monitoring the frequency of specimen handling problems (such as the use of an improper blood collection tube, inadequate mixing of blood specimens with anticoagulant after collection), and delays in specimen transport; identifying clients who repeatedly refer unacceptable specimens or improperly complete requisition forms and documentation of its efforts to reduce the recurrence of these problems. The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. 2. In

	an interview at 10:34 hours on 8/30/2018 in the laboratory, the Laboratory Manager stated the laboratory had not developed a formal written quality assessment policy. This is a repeat deficiency from the previous CLIA recertification survey on September 22, 2016.
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 policies and procedures, surveyor observations, and interview with facility personnel, the laboratory failed to follow the established step by step procedure for processing urine specimens for urine microscopic analysis for 7 of 7 months between January 1, 2018 and August 29, 2018. The findings included: 1. Based on review of the laboratory's policy "Microscopic Exam of Urine Sediment", on page 2 of 4, describes the procedure for processing urine specimens for urine microscopic element analysis. The procedure states: "2. Centrifuge tubes for five (5) minutes at 400g. (1900 rpm with a 9.6 cm radius head)." 2. At 09:34 hours on 08/29 /2018 in the laboratory, the surveyor observed the Thermofischer AccuSpin 8C centrifuge setting as follows: 2.4 x 1000 RPM for 5 minutes. Review of the Thermofischer AccuSpin 8C operator's manual (20059497-a) indicated this was 2400 RPM and 700 g for 5 minutes. 3. At 09:34 hours on 8/29/2018 in the laboratory, the Laboratory Manager confirmed that the laboratory had routinely processed specimens for urine microscopic analysis at a greater centrifugal force than indicated in the procedure. Key: g - relative centrifugal force RPM -revolutions per minute RCF - relative centrifugal force cm - centimeter
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 Osom Ultra hCG Combo test instructions for use, quality control records, patient test records, laboratory policies and procedures, and interview with facility personnel, the laboratory failed to perform a positive and negative control each day of testing for 6 of 8 days between February 11, 2018 and July 27, 2018. The findings included: 1. Review of the Osom Ultra hCG Combo test instructions for use (Non-waived for Serum), under EXTERNAL CONTROL, states the following: "External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested before using a new lot, untrained operator, or a new shipment or kit as good laboratory testing practice and that users follow federal, state, and local guidelines for quality control requirements." 2. Based on review of quality control records for the Osom Ultra hCG Combo test, Quality Control was performed on the following dates: 2 /11/2018 3/15/2018 5/24/2018 6/12/2018 8/27/2018 3. Based on review of patient test records, Sample 101353 was analyzed on 2/16/2018. No quality control was performed and documented on 2/16/2018 Sample 102451 was analyzed on 3/15/2018. Quality control was performed and acceptable on 3/15/2018. Samples 102977 and 102982 were analyzed on 3/31/2018. No quality control was performed and documented on 3/31/2018. Samples 103400 and 103445 were analyzed on 4/12/2018. No quality control was performed and documented on 4/12/2018. Sample 104381 was analyzed on 5/6/2018. No quality control was performed and documented on 5/6 /2018. Sample 104750 was analyzed on 5/16/2018. No quality control was performed and documented on 5/16/2018. Sample 1054885 was analyzed on 6/12/2018. Quality control was performed and acceptable on 6/12/2018. Samples 1056832 and 1056844 were analyzed on 7/27/2018. No quality control was performed and documented on 7 /27/2018. Between 2/11/2018 and 7/27/2018, patient specimens were analyzed on 6 of 8 days when the laboratory failed to perform both a positive and negative control material. 4. In an interview at 11:34 hours on 8/29/2018 in the laboratory, when asked if the laboratory had developed and Individualized Quality Control Plan (IQCP) to reduce the frequency of quality control testing, the Laboratory Manager stated " we do not have an IQCP for serum hCG".
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of microbiology media quality control documentation for 2017 and 2018, confirmed by staff interview, the laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response for 8 of 8 lots or shipments between May 1, 2018 through August 29, 2018. The findings included: 1. Microbiology quality control documentation for May 1, 2018 through August 29, 2018 was reviewed. For

	MacConkey II media, the laboratory's documentation consisted of documenting the physical characteristics of the media when compromised and reporting any deterioration in the media to the manufacturer. The following lots/shipments had documentation of the review of physical characteristics: Media: MacConkey Agar II 20/Pack Lot: 8060512 Inspected on 5/2/2018 Media: MacConkey Agar II 20/Pack Lot: 807753 Inspected on 5/16/2018 Media: MacConkey Agar II 20/Pack Lot: 8116614 Inspected on 5/23/2018 Media: MacConkey Agar II 20/Pack Lot: 8137982 Inspected on 7/6/2018 Media: MacConkey Agar II 20/Pack Lot: 8137982 Inspected on 7/12/2018 Media: MacConkey Agar II 20/Pack Lot: 8145936 Inspected on 7/19 /2018 Media: MacConkey Agar II 20/Pack Lot: 8145936 - Same lot, new shipment Inspected on 7/25/2018 Media: MacConkey Agar II 20/Pack Lot: 8201724 Inspected on 08/22/2018 A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment. A sample from each batch of media is sufficient as a check for: Sterility, if it is autoclaved or filtered during preparation; Ability to support growth, using at least one organism to demonstrate the ability of the media to support growth; Selectivity and/or inhibition, using at least one organism to confirm its selective characteristic, and at least one organism to confirm it's inhibitory characteristic; and Biochemical response, using at least one organism which will produce the expected reaction (positive control) and with at least one organism which will not produce the expected reaction (negative control). American Type Culture Collection (ATCC) control organisms are not necessarily required. However, if the laboratory uses "in-house" isolates for control organisms, it must have established reactivity for each organism. 2. Review of the BBL MacConkey II Agar instructions for use (L007388, Rev. 10, November 2015), under VI Principles of the Procedure, states the following: "MacConkey II Agar is a selective and differential medium. It is only slightly selective since the concentration of bile salts, which inhibits gram-positive microorganisms is low in comparison with other enteric plating media. Crystal violet also is included in the medium to inhibit the growth of gram-positive bacteria, especially enterococci and staphylococci. Differentiation of enteric microorganisms is achieved by the combination of lactose and the neutral red indicator, Colorless or pink to red colonies are produced depending upon the ability of the isolate to ferment the carbohydrate." 3. In an interview at 11:55 hours on 8/29 /2018 in the laboratory, the Laboratory Manager stated she was unaware of the current regulatory requirement for per lot, shipment or batch checks on media other than Chocolate Agar and that no checks had been performed on media other than Chocolate Agar. This is a repeat deficiency from the previous CLIA recertification survey on September 22, 2016.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of the OPTI CCA-TS2 blood gas analyzer operator's manual, quality control records, patient test records, and interview with facility personnel, the

	laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 5 of 5 patients tested between May 31, 2018 and August 16, 2018. The findings included: 1. Based on review of the Opti-CCA-TS2 blood gas analyzer operator's manual (PD7301, Rev.B), on page 9-10, the document states the following: "9.5.6 Quality Control On initial use of each shipment of cassettes, and at 1 month intervals thereafter, validation of the lot should be performed by analysis of OPTI Medical blood gas, electrolyte, metabolite, tHb and So2 controls (OPTI CHECK or OPTI CHECK PLUS). This material should provide target values for all measure parameters over a range of measurement values typically seen in each laboratory." 2. Based on review of patient records and quality control records: A patient specimen was tested on 8/16/2018 at 22:37 hours. A patient specimen was tested on 7/19/2018 at 19:42 hours. A patient specimen was tested on 7/3/2018 at 05:29 hours. A patient specimen was tested on 6/25/2018 at 13:14 hours. A patient specimen was tested on 5 /31/2018 at 14:00 hours. Based on review of function check records and quality control records, the liquid external quality control materials were not performed on 8 /16/2017, 7/19/2018, 7/3/2018, 6/25/2018, or 5/31/2018. 3. Based on review of patient records, testing was performed on a specimen from patient 10010391 on 8/10/2018. The laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 1 of 1 day on August 10, 2018. 4. In an interview with the Laboratory Director on 8/28/2018 at 09:42 hours in the conference room, the Laboratory Manager stated the laboratory had not implemented an Individualized Quality Control Plan to modify the frequency of testing liquid controls at least one level every 8 hours of patient testing to include both a low and high control each day of patient testing to the frequency in the operator's manual of each lot of sensor cassettes and at 1 month intervals thereafter, validation should be performed by analytes of OPTI check or OPTI check plus.
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 policies and procedures, quality control records, patient test records, surveyor observations, and interview with facility personnel, the laboratory failed to 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 in 2017 and 2018. The laboratory's quality assessment activities failed to monitor, assess, and correct the following: 1. Based on review of policies and procedures, surveyor observations, and interview with facility personnel, the laboratory failed to follow the established step by step procedure for processing urine specimens for urine microscopic analysis for 7 of 7 months between January 1, 2018 and August 29, 2018. Refer to D5403. Based on review of Osom Ultra hCG Combo test instructions for use, quality control records, patient test records, laboratory policies and procedures, and interview with facility personnel, the laboratory failed to perform a positive and negative control each day of testing for 6 of 8 days between February 11, 2018 and

	July 27, 2018. Refer to D5449. 2. Based on review of microbiology media quality control documentation for 2017 and 2018, confirmed by staff interview, the laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response for 8 of 8 lots or shipments between May 1, 2018 through August 29, 2018. Refer to D5477. 3. Based on a review of the OPTI CCA-TS2 blood gas analyzer operator's manual, quality control records, patient test records, and interview with facility personnel, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 5 of 5 patients tested between May 31, 2018 and August 16, 2018. Refer to D5537. 4. Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or the facility of which it is a part. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation. QA of the Analytic System includes assessing: o Test procedures; o Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; o Specimen and reagent storage condition; o Equipment/instrument/test /system maintenance and function checks; o Establishment and verification of method performance specifications; o Calibration and calibration verification; o Control procedures; o Comparison of test results; o Corrective actions; and o Test records. Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services. 5. In an interview at 10:34 hours on 8/30/2018 in the laboratory, the Laboratory Manager stated the laboratory had not developed a formal written quality assessment policy. This is a repeat deficiency from the previous CLIA recertification survey on September 22, 2016.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the Sysmex XS-1000i hematology analyzer operator's manual, verification studies, patient records, and interview with facility personnel, the laboratory failed to ensure pertinent reference intervals were used on the final patient report for 4 of 4 parameters evaluated as part of a complete blood count. The findings included: 1. Based on review of the laboratory's procedure "COMPLETE BLOOD COUNT OF WHOLE BLOOD ON THE SYSMEX XS-Series", approved by the laboratory director on 3/27/2012, on

	page 38 of 40, the laboratory failed to define the normal reference ranges for components of a complete blood count. Under IX REPORTING RESULTS, the procedure states "Complete this section with your laboratory's normal reference range". The section is blank. A note in the right-hand column states " See LIS". 2. Based on review of the Sysmex XS-1000i hematology analyzer operator's manual (Date of Last Revision: November 2010), on pages 1-5 and 1-6, the manufacturer of the hematology analyzer provides the following: "1.6 Reference Intervals Reference intervals (Normal Population Reference Ranges) were developed for the XS-100i /XS800i using normal individuals. the range for each parameter is calculated for 95 percent confidence intervals. Parameter: White Blood Cell count (WBC) Females: 3.98 -10.04 x 1000 per microliter Males: 4.23 - 9.07 x 1000 per microliter Parameter: Red Blood Cell count (RBC) Females: 3.93 - 5.22 x 1,000,000 per microliter Males: 4.63 -6.08 x 1,000,000 per microliter Parameter: Hemoglobin (HGB) Females: 11.2 - 15.7 grams per deciliter Males: 13.7 - 17.5 grams per deciliter Parameter: Platelet count (PLT) Females: 182 - 369 x 1000 per microliter Males: 163 -337 x 1000 per microliter 3. Based on a random review of 6 patient specimens, the laboratory was using the following reference ranges on the patient final report: Parameter: White Blood Cell count (WBC) Females: 4.6 - 10.2 x 1000 per microliter Males: 4.6 - 10.2 x 1000 per microliter Parameter: Red Blood Cell count (RBC) Females: 3.90 - 5.00 x 1,000,000 per microliter Males: 4.50 -5.70x 1,000,000 per microliter Parameter: Hemoglobin (HGB) Females: 12.0 - 16.0grams per deciliter Males: 14.0 - 18.0 grams per deciliter Parameter: Platelet count (PLT) Females: 140 - 440 x 1000 per microliter Males: 140 - 440 x 1000 per microliter 4. Based on review of the installation verification study for the Sysmex XS-1000i hematology analyzer, there was no evidence that laboratory evaluated reference ranges as required at 42 CFR 493.1253 prior to performing patient testing. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 5. In an interview at 10:24 hours on 8/30/2018 in the laboratory, the Laboratory Manager stated the laboratory was not sure of the origin of the reference ranges in use, but they may have come from the Abbott hematology analyzer that was previously in use prior to the verification of the Sysmex XS-1000i.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of policies and procedures, reference ranges, patient records, and interview with facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493. 1291 for 2017 and 2018. The findings included: 1. Based on review of the laboratory's policies and procedures, the Sysmex XS-1000i hematology analyzer operator's manual, verification studies, patient records, and interview with facility personnel, the

	laboratory failed to ensure pertinent reference intervals were used on the final patient report for 4 of 4 parameters evaluated as part of a complete blood count. Refer to D5807. Quality Assessment (QA) of the Postanalytic System includes assessing practices/issues related to test reports. Examples include monitoring and evaluating the accuracy and completeness of the laboratory's test reports (i.e., patient information, test results, normal ranges, and the disposition of unacceptable specimens), and the laboratory's turn-around times and procedures for notification of test results e.g., routine tests, STATS, abnormal or panic values. If the laboratory uses an LIS, the laboratory must have a mechanism to periodically verify the accuracy of: Its calculated data; Its results sent to interfaced systems; and Patient specific data. 2. In an interview at 10:34 hours on 8/30/2018 in the laboratory, the Laboratory Manager stated the laboratory had not developed a formal written quality assessment policy.
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 on review of quality control policies, procedures, and records, and interview with facility personnel, the Laboratory Director failed to ensure the quality control program is established and maintained to assure the quality of laboratory services provided. The findings included: 1. Based on review of Osom Ultra hCG Combo test instructions for use, quality control records, patient test records, laboratory policies and procedures, and interview with facility personnel, the Laboratory Director failed to ensure the laboratory performed a positive and negative control each day of testing for 6 of 8 days between February 11, 2018 and July 27, 2018. Refer to D5449. 2. Based on a review of the OPTI CCA-TS2 blood gas analyzer operator's manual, quality control records, patient test records, and interview with facility personnel, the Laboratory Director failed to ensure the laboratory tested one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 5 of 5 patients tested between May 31, 2018 and August 16, 2018. Refer to D5537.
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 quality control policies, procedures, and records, and interview with facility personnel, the Laboratory Director failed to ensure the quality control program is established and maintained to assure the quality of laboratory services provided. The findings included: Based on review of microbiology media quality

	control documentation for 2017 and 2018, confirmed by staff interview, the Laboratory Director failed to ensure the laboratory checked each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response for 8 of 8 lots or shipments between May 1, 2018 through August 29, 2018. Refer to D5477.
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 policies and procedures, surveyor observations, quality control records, patient records, and interview with facility personnel, the Laboratory Director failed to 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 for 2016, 2017, and 2018. The findings included: 1. Based on review of policies and procedures, competency assessment documentation, and interview with facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493. 1231 through 493.1236 for 2016 and 2017. Refer to D5291. Based on review of policies and procedures and interview with facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242 for 2016 and 2017. Refer to D5391. Based on review of laboratory policies and procedures, quality control records, patient test records, surveyor observations, and interview with facility personnel, the laboratory failed to 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 in 2017 and 2018. Refer to D5791. Based on review of policies and procedures, reference ranges, patient records, and interview with facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems specified in 493.1291 for 2017 and 2018. Refer to D5891.