

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2119637	(X3) Date Survey Completed 11/26/2018
Name of Provider or Supplier Medella Urgent Care Plc	Street Address, City, State 10130 Loutta Rd Ste L, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5024 - 42 C.F.R. 493.1215 Condition: Hematology; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Review of quality control records, observations, patient test records and interview of facility personnel found that the laboratory failed to follow the manufacturers instructions for testing quality control materials once every 30 days when using the Piccolo Express Comprehensive Metabolic Panel (CMP). Findings included: 1. Review of quality control records found that the laboratory tested quality control materials for each of the CMP disc lot numbers used to test patient specimens as follows: November 6, 2016 - lot 6311 AB1 December 7, 2016 - lot 6311 AB1 January 6, 2017 - lot 6411 AC1. February 7, 2017 - lot 6432 BC 4. February 27, 2017 - lot 6432 BC 4. March 7, 2017 - lot 7034 AB17 April 21, 2017 - lot 7071 AC8. May 12, 2017 - lot 7071 AC8. June 5, 2017 - lot 7071 AC8. July 8, 2017 - lot 7071 AC8. July 23, 2017 - lot 7203 AC7 August 9, 2017 - lot 7144 AC7. October 12, 2017 - lot 7203 AC7. November 3, 2017 - lot 7203 AC7. December 3, 2017 - lot 7203 AC7. March 7,</p>

2018 - lot 7494BB4. August 5, 2018 - lot 8202 GC7. September 5, 2018 - lot 8202 GC7. 2. Observations made during the tour the facility found that the laboratory was currently using the Piccolo CMP disc lot 8301 AB4 expiration 2019-07-23. 3. Review of patient test records found that the laboratory tested patient specimens using the following disc lots without testing quality control materials. May 19, 2018 - patient 6047 was tested using disc lots 8071AA1 without documentation of quality control being tested. July 12, 2018 patient 6777 was tested using disc lot 8116 AB) without documentation quality control being tested. 4. Interview of the technical consultant conducted on November 26, 2018 at 1:23 PM found that the laboratory does approximately 10 to 15 CMP per month. He went on to say that they have problems keeping supplies for patient testing and would sometimes borrow from another facility.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of the laboratory American Proficiency Institute (API) proficiency testing records from 2017 and 2018 and confirmed in interview, the laboratory failed to retain instrument printouts and attestation statements for 5 of 6 Hematology events and 1 of 1 Chemistry event. Findings were: 1. Review of the API proficiency testing records from 2017 and 2018 revealed 5 of 6 Hematology events with no documentation of the instrument printouts and attestation statements. 2017 Hematology Event 1 2017 Hematology Event 2 2017 Hematology Event 3 2018 Hematology Event 1 2018 Hematology Event 2 2. Review of the API proficiency testing records from 2017 revealed 1 of 1 Chemistry event with no documentation of the instrument printouts and attestation statements. 2017 Chemistry Event 1 3. An interview with the technical consultant on 11/26/18 at 1005 hours in the break room confirmed the above findings.

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review of the laboratory quality control records and confirmed in interview, the laboratory failed to retain the manufacturer's assay information sheets for quality

	<p>control for 7 of 8 months for a minimum of 2 years. Findings were: 1. Random review of the laboratory quality control from April 2018 to November 2018 revealed no documentation of the package insert for the Sysmex Eithcheck-3WP X-tra quality control used for 7 of 8 months. April 2018 May 2018 June 2018 July 2018 August 2018 September 2018 October 2018 Note: Laboratory quality control records maintained had no documentation of the lot number used. 2. An interview with the technical consultant on 11/26/18 at 1405 hours in the break room confirmed the above findings.</p>
<p>D5024</p>	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, Hematology records, patient test results, observations, and interviews, the laboratory failed to meet applicable requirements in the specialty of hematology as evidence by: 1. The laboratory failed to document a stability study that substantiated the conclusions of their laboratory policy for CBC (complete blood count) for the Sysmex Poch-100i hematology analyzer (See D5311-A). 2. The laboratory failed to follow its policy to label patient specimens for CBC analysis on the Sysmex Poch-100i hematology analyzer (See D5311-B). 3. The laboratory failed to follow the manufacturer's instructions and establish its own acceptable ranges for the Sysmex Eightcheck-3WP X-Tra hematology control for the the Sysmex Poch-100i hematology analyzer (See 5411). 4. The laboratory failed to have documentation to monitor the operating temperature and humidity for CBC (complete blood count) patient testing on the Sysmex Poch-100i hematology analyzer (See D5413). 5. The laboratory failed to document complete verification studies for the Sysmex Poch-100i hematology analyzer (See D5421-II). 6. The laboratory failed to document the manufacturer required daily maintenance for the Sysmex Poch-100i hematology analyzer (See D5429).</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2017 and 2018 personnel records, laboratory policies, and confirmed in interview, the laboratory failed to document the competency assessment for 1 of 1 technical consultant. Findings were: 1. Review of the 2017 and 2018 personnel records revealed no documentation of the competency assessments for 1 of 1 technical consultant (hire date 08/2016). 2. An interview with the technical consultant on 11/26/18 at 1130 hours confirmed the above findings.</p>
<p>D5311</p>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</p>

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

A. Based on review of the manufacturer's instructions, laboratory policy, laboratory patient records, and confirmed in interview, the laboratory failed to document a stability study that substantiated the conclusions of their laboratory policy for CBC (complete blood count) for the Sysmex Poch-100i hematology analyzer. Findings were: 1. Review of the Sysmex Poch-100i implementation manual (MKT-30-1003, Rev 9, December 2011) revealed "stability studies are performed to determine the readiness of a sample for CBC and differential count analysis. Short-term stability is performed with fresh samples drawn and analyzed at intervals within 1 hour. Long-term stability is conducted under storage conditions and over a period of time defined by the laboratory as acceptable for specimen analysis." 2. Review of the laboratory policy Complete Blood Count - Poch-100i (LAB-01, implemented 09/15/16) revealed "EDTA blood samples stored at 4C with normal results may be analyzed up to 24 hours without significant loss of differential stability. Sample stability at room temperature is 8 hours. Samples stored at room temperature may exhibit an increase in MCV, and HCT and a decrease in MCHC after 16 hours. These changes may be minimized by refrigeration." 3. Review of the laboratory verification records for the Sysmex Poch-100i hematology analyzer revealed no documentation of the stability studies to substantiate the laboratory policy to perform CBC testing up to 24 hours refrigerated or at room temperature for 8 hours. 4. An interview with the technical consultant on 11/26/18 at 1105 hours in the breakroom confirmed the above findings. He was unaware the laboratory was required to perform stability studies. B. Based on surveyor observations, laboratory policy, and confirmed in interview, the laboratory failed to follow its policy to label patient specimens for CBC analysis on the Sysmex Poch-100i hematology analyzer. Findings were: 1. Review of the laboratory policy Labeling Specimens (PH-03, implemented 09/15/16) revealed "all specimens MUST be labeled at the time of collection and in the presence of the patient. All specimens should be labeled with the following: patient's name, medical record number, date and time of collection and initials of the collector." 2. Observations on 11/26/18 at 1050 hours revealed the laboratory performed CBC analysis on patient ID 5173. Review of the laboratory specimen revealed no documentation of the date and time of collection and initials of the collector, per the laboratory policy. 3. Review of the patient final report revealed the laboratory reported the CBC analysis for patient ID 5173 with a date and time of collection of 11/26/18 at 1045 hours. 4. An interview with the technical consultant on 11/26/18 at 1105 hours in the laboratory confirmed the above findings. He acknowledged that the specimen tested had no documentation of the date and time on the specimen itself. He stated that he "guesstimated" the time and that the collector was "in training."

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic

systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions and establish its own acceptable ranges for the Sysmex Eightcheck-3WP X-Tra hematology control for the the Sysmex Poch-100i hematology analyzer (See 5411). 2. The laboratory failed to have documentation to monitor the operating temperature and humidity for CBC (complete blood count) patient testing on the Sysmex Poch-100i hematology analyzer (See D5413). 3. The laboratory failed to perform a complete verification study for CKMB (Creatine Kinase Isoenzyme), Myoglobin and Troponin I testing using the Triage Cardiac Panel on the Alere Triage Meter (See D5421-I). 4. The laboratory failed to document complete verification studies for the Sysmex Poch-100i hematology analyzer (See D5421-II). 5. The laboratory failed to document the manufacturer required daily maintenance for the Sysmex Poch-100i hematology analyzer (See D5429). 6. The laboratory failed to establish and monitor a quality control plan for the Triage Cardiac Panel in the seven months it was used for testing patient specimens (See D5441).

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's instructions, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions and establish its own acceptable ranges for the Sysmex Eightcheck-3WP X-Tra hematology control for the the Sysmex Poch-100i hematology analyzer. Findings were: 1. Review of the package insert for the Sysmex Eightcheck-3WP X-Tra hematology control (350493-2, Rev15, 02/2013) revealed "assay means are not intended for use as analyzer QC file target values. For effective QC, each laboratory should set its own target values. Sysmex recommends that each laboratory establish this QC target value by collecting at least 10 data points per control level over 5 days. The mean QC target values from this initial data collection should be within the expected ranges listed on the package insert. Sysmex recommends as an option that each laboratory either establish their own QC file limits based on the laboratory's historical coefficient of variation (CV) by using historical data or by using the limits provided in the package insert with each lot of Sysmex Eightcheck-3WP X-Tra." 2. Review of the laboratory quality control records from November 2018 revealed no documentation of the laboratory establishing its own acceptable target ranges, per the manufacturer's instructions. Lot 83110710, exp 2/13/19 Lot 83110711, exp 2/13/19 Lot 83110712, exp 2/13/19 3. Random review of the laboratory patient test records

from November 2018 revealed the laboratory performed patient testing with the above quality control lot with no documentation of establishing its own acceptable range. Patient ID 5486 8766 3863 8682 4. An interview with the technical consultant on 11/26/18 at 1345 hours in the breakroom confirmed the above findings. He was unaware the laboratory was required to establish its own ranges. He stated the laboratory always entered the manufacturer's expected ranges and used it as their own.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to have documentation to monitor the operating temperature and humidity for CBC (complete blood count) patient testing on the Sysmex Poch-100i hematology analyzer. The findings were: 1. Review of the Sysmex Poch-100i instructions for use (Revised June 2008) revealed under "Operating Environment: Indoor Use Temperature 18 to 30 oC) Humidity 30 - 85% Relative humidity 2. Random review of the laboratory environmental records from October 2018 to November 2018 revealed no documentation of the laboratory monitoring temperature and humidity for 17 of 17 days when the laboratory performed CBC patient testing. 11/19/18 11/17/18 11/12/18 11/11/18 11/10/18 11/04/18 10/31/18 10/30/18 10/27/18 10/26/18 10/20/18 10/19/18 10/17/18 10/15/18 10/12/18 10/10/18 10/04/18 3. Review of the patient test logs from October - November 2018 revealed the laboratory performed patient testing on the above dates with no documentation of the laboratory monitoring the temperature and humidity. Date Acc # 11/19/18 8766 11/07/18 6631 11/12/18 5486 11/11/18 6439 11/10/18 1839 11/04/18 5982 10/31/18 8462 10/30/18 8455 10/27/18 8407 10/26/18 8389 10/20/18 3779 10/19/18 8267 10/17/18 5692 10/15/18 8222 10/12/18 8089 10/10/18 4659 10/04/18 5300 4. An interview with the technical consultant on 11/26/18 at 1435 hours in the break room confirmed the above findings. He acknowledged that the laboratory should maintain the environmental records in the laboratory.

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:
Based on observation, review of laboratory supplies, and confirmed in interview, the

laboratory failed to indicate the open expiration date of its reagent used for its Sysmex Poch-100i hematology analyzer. Findings were: 1. During a tour of the laboratory on 11/26/18 at 1015 hours the surveyor observed an open pocH pack D (lot Y8022, exp 3/20/22) and pocH-pack L (lot Y8005, exp 6/22/19) reagents with no documentation of the open expiration date. 2. A review of the package insert for the above reagents revealed the pocH-100i Pack D has an opened stability for 60 days; and the pocH-100i pack L has an opened stability of 90 days. 3. An interview with the technical consultant on 11/26/18 at 1020 hours in the laboratory confirmed the above findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory verification studies, patient test records and interview of facility personnel, the laboratory failed to perform a complete verification study for CKMB (Creatine Kinase Isoenzyme), Myoglobin and Troponin I testing using the Triage Cardiac Panel on the Alere Triage Meter. Findings included: 1. Review of the verification study for CKMB and Troponin I performed on October 6, 2016 found that the laboratory tested one level of quality control material 10 times for precision. The laboratory tested five levels of calibration verification material running each specimen once on October 6, 2016. There was no documentation that the data had been reviewed and evaluated to determine whether it met the manufacturers specifications for accuracy, precision and reportable range. There was no evidence of reference range establishment studies available for review. 2. Review of patient test records found that the laboratory tested 12 patient specimens between October 6, 2016 and April 26, 2017 without verifying the accuracy, precision and reportable range of the Triage Cardiac Panel. 3. Interview the technical consultant conducted on November 26, 2018 at 12:51 PM confirmed that the data offered as the verification studies for the Triage Cardiac Panel had not been evaluated for accuracy, precision and reportable range against the manufacturers claims. 38387 II. Based on review of the manufacturer's instructions, laboratory verification records, laboratory patient records, and confirmed in interview, the laboratory failed to document complete verification studies for the Sysmex Poch-100i hematology analyzer. A. reference range study B. Accuracy/Precision C. Linearity (reportable range verification) D. Stability Study Findings were: A. Reference Range 1. Review of the laboratory final patient reports revealed the laboratory reports for complete blood count on the Sysmex Poch-100i hematology analyzer included the following analytes: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYMP, NEU, and MXD. 2. Review of the Sysmex Poch-100i implementation manual (MKT-30-1003, Rev 9, December 2011) revealed "reference range describe analyte levels associated with persons who are considered healthy...select at least 40 samples...analyze no more than 25% of the total sample size on one given day. Analyze CBC and differential blood samples on the pocH-100i within 4 hours of collection...calculate the reference range for each parameter using +/- 2 S.D including 95% of the population." 3. Review of the

laboratory verification records for the Sysmex Poch-100i hematology analyzer (SN G4715) revealed no documentation of the laboratory verifying the following adult and pediatric reference ranges for the following analytes. Adult (>14 years) WBC: 3.8 - 10.3 10³/uL RBC: 3.98 - 5.24 1-³/uL Hgb (female): 12 - 15.4 10³/uL Hgb (male): 12.3 - 18.8 10³/uL Hct: 36.1 - 46.8% MCV: 81.9 - 96.0 fL MCH: 27.6 - 33.4 pg MCHC: 31.9 - 36.3 g/dL PLT: 128 - 342 10³/uL Neutrophils: 40 - 80% Lymphocytes: 25 - 35% Monocytes: 2- 10 % Eosinophils: 0 - 5 % Basophils: 0 - 1% Pediatrics (2-14 years) WBC: 4.5 - 11.5 10³/uL RBC: 4.0 - 5.30 1-³/uL Hgb (female): 10.7 - 13.6 10³/uL Hgb (male): 10.5 - 14.8 10³/uL Hct: 31.7 - 43.9% MCV: 82.2 - 99.5 fL MCH: 26.2 - 34 pg MCHC: 30.0 - 35.6 g/dL PLT: 165 - 405 10³/uL Neutrophils: 35 - 80% Lymphocytes: 25 - 65% Monocytes: 2- 10 % Eosinophils: 0 - 5 % Basophils: 0 - 1% 4. Random review of the laboratory records from January to November 2018 revealed the laboratory performed CBC (complete blood count) testing using the Sysmex Poch-100i hematology analyzer. Adults Date Acc 01/09/18 4572 02/01/18 4879 03/01/18 5288 04/01/18 5618 07/12/18 6777 10/12 /18 3866 10/12/18 8089 11/12/18 5486 Pediatrics Date Acc 09/01/18 7499 5. An interview with the technical consultant on 11/26/18 at 1105 hours in the breakroom confirmed the above findings. B. Accuracy/Precision 1. Review of the laboratory final patient reports revealed the laboratory reports for complete blood count on the Sysmex Poch-100i hematology analyzer included the following analytes: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYMP, NEU, and MXD. 1. 2. Review of the laboratory verification records for the Sysmex Poch-100i hematology analyzer (SN G4715) revealed no documentation of the laboratory verifying the accuracy and precision for the WBC (white blood cell) differential that included the analytes Lymphocytes, Mixed cells, and Neutrophils. 3. Random review of the laboratory reports from January to November 2018 revealed the laboratory performed CBC testing with WBC differential using the Sysmex Poch-100i hematology analyzer. Date Acc 01/09/18 4572 02/01/18 4879 03/01/18 5288 04/01/18 5618 07/12/18 6777 10/12 /18 3866 10/12/18 8089 11/12/18 5486 09/01/18 7499 4. An interview with the technical consultant on 11/26/18 at 1105 hours in the breakroom confirmed the above findings. C. Linearity (reportable range verification) 1. Review of the laboratory Sysmex Poch-100i hematology analyzer revealed the laboratory used the manufacturer's linearity limits. WBC 1.0 - 99.9 x 10³/L RBC 0.3 - 7.0 x 10⁶/L HGB 0.1 - 25.0 g/dL HCT 10.0 - 60 % PLT 10 - 999 x 10³/L 2. Review of the laboratory verification records for the Sysmex Poch-100i revealed no documentation of the laboratory verifying the above linearity limits. 3. An interview with the technical consultant on 11/26/18 at 1105 hours in the breakroom confirmed the above findings. D. Stability study 1. Review of the laboratory verification records for the Sysmex Poch-100i hematology analyzer revealed no documentation of the stability studies to substantiate CBC testing up to 24 hours refrigerated or at room temperature for 8 hours. Cross refer to D5311 2. An interview with the technical consultant on 11/26/18 at 1105 hours in the breakroom confirmed the above findings. He was unaware the laboratory was required to perform stability studies. key: WBC - white blood cell RBC - red blood cell Hgb - hemoglobin Hct - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - Mean corpuscular hemoglobin concentration PLT - platelet

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 manufacturer's instructions, laboratory maintenance records, patient test logs and confirmed in interview the laboratory failed to document the manufacturer required daily maintenance for the Sysmex Poch-100i hematology analyzer. Findings were: 1. Review of the Poch-100i instructions for use (Revised June 2008) revealed the following required daily maintenance. Daily - Check instrument status - Perform Shutdown 2. Random review of the October and November 2018 maintenance log revealed no documentation of the required daily maintenance for 17 of 17 days when the laboratory performed CBC patient testing. 11/19/18 11/17/18 11/12/18 11/11/18 11/10/18 11/04/18 10/31/18 10/30/18 10/27/18 10/26/18 10/20/18 10/19/18 10/17/18 10/15/18 10/12/18 10/10/18 10/04/18 3. Review of the patient test logs from October - November 2018 revealed the laboratory performed patient testing on the above dates. Date Acc # 11/19/18 8766 11/07/18 6631 11/12/18 5486 11/11/18 6439 11/10/18 1839 11/04/18 5982 10/31/18 8462 10/30/18 8455 10/27/18 8407 10/26/18 8389 10/20/18 3779 10/19/18 8267 10/17/18 5692 10/15/18 8222 10/12/18 8089 10/10/18 4659 10/04/18 5300 4. An interview with the technical consultant on 11/26/18 at 1435 hours in the break room confirmed the above findings.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, manufacturer's product inserts, quality control records, patient test records and staff interview, the laboratory failed to establish and monitor a quality control plan for the Triage Cardiac Panel in the seven months it was used for testing patient specimens. Findings included: 1. Review of the laboratory's policy titled triage meter Pro Cardiac Panel (signed by the laboratory director October 10, 2016) found on page 5 of six under the heading external quality control testing - "external QC will be run every day. Whenever patient testing occurs for a period of 10 days. After the tenth day, a updated IQ CP plan will represent how often external QC would be run." 2. Review of the manufacturer's product insert found on page 7 - "users should follow government guidelines (for example, federal, state or local) and or accreditation requirements for quality control." 3. Review of quality control records found that the laboratory tested two levels of quality control material using the Triage Cardiac Panel on the following dates: October 6, 2016. October 10, 2016. October 26, 2016. November 1, 2016. November 10, 2016. November 11, 2016. December 7, 2016. December 25, 2016. January 7, 2017. February 20, 2017. March 6, 2017. April 26, 2017. 4. Review of patient test records found that the laboratory tested 15 patients using the Triage

Cardiac Panel on the following dates: November 10, 2016 - two patient specimens tested. November 11, 2016 -two patient specimens tested November 13, 2016 - one patient specimen tested with no evidence of external quality controls being tested. November 15, 2016 - one patient specimens tested with no evidence of external quality control being tested. November 24, 2016 - one patient specimen tested with no evidence of external quality control being tested. December 5, 2016 - two patient specimens tested with no evidence of external quality control being tested. December 6, 2016 - one patient specimen tested with no evidence of external quality control being tested. December 16, 2016 - one patient specimens tested with no evidence of external quality control being tested. December 19, 2016 - one patient specimen tested with no evidence of external quality control being tested. December 28, 2016 - one patient specimen tested with no evidence of external quality control being tested. December 29, 2016 - one patient specimens tested with no evidence of external quality control being tested. 5. Interview of the technical consultant conducted on November 26, 2018 at 11:18 AM confirmed that the laboratory failed to test at least two levels of external quality control material each day of patient testing when using the Triage Cardiac Panel. The laboratory intended to develop an individualized quality control plan (I QC P) to reduce the frequency of testing of external quality control materials. After 10 days of quality control testing. However, the laboratory decided to discontinue using the Triage Cardiac Panel due to the cost per test.

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:
 Review of personnel files, laboratory records, quality control records and interview of facility personnel found the laboratory failed to establish written policies and procedures (Quality Assurance) for an ongoing mechanism to monitor, assess and correct problems identified in the analytic system in order to ensure accurate patient results. Findings Included: 1. The laboratory failed to verify the performance specifications of the Alere Triage Cardiac Panel to ensure it met the manufacturers claims for accuracy, precision, reportable range and establish a reference range suitable for the patient population served by the laboratory. (See D5421-I) 2. The laboratory failed to document complete verification studies for the Sysmex Poch-100i hematology analyzer. (see D5421-II) 3. The laboratory failed to follow the manufacturer's instructions and establish its own acceptable ranges for the Sysmex Eightcheck-3WP X-Tra hematology control for the the Sysmex Poch-100i hematology analyzer. (See D5411) 3. The Laboratory failed to establish and maintain a quality control program for the Alere Triage Cardiac Panel . (See D5441)

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	<p>This CONDITION is not met as evidenced by: Based on review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6013, and D6020)</p>
<p>D6007</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory preanalytic and analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology. Refer to D5311-A, B and D5411.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory verification records, and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies for the Sysmex Poch-100i hematology analyzer and Triage Cardiac Panel on the Alere Triage Meter. (Refer to D5421-I,II)</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Review of quality control records and interview of facility personnel found that the laboratory director failed to ensure that the quality control program was established and maintained for Chemistry. (See D5441)</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory policies, verification studies, calibration records, and confirmed in interview, the technical consultant failed to provide technical oversight of the laboratory. (Refer to D6040, D6042, and D6049)</p>
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records, calibration records, and patient test records found that the technical consultant failed to verify that the Alere Triage Cardiac Panel met the manufacturer's specifications for accuracy, precision and reportable range. (See D5421)</p>
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the quality control program had been established and maintained for the of Alere Triage Cardiac Panel using the Alere triage meter. (See D5441)</p>
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records,</p>

proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the CMS form 209, personnel records and verified by interview, the Technical Consultant failed to document competency evaluations that included review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for 5 of 9 testing personnel for the moderately complex testing for Sysmex Poch-100i hematology analyzer. Findings were: 1. A review of the facility's personnel files revealed no documentation of the competency evaluations that included review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for 5 of 9 testing personnel for the moderately complex testing for Sysmex Poch-100i hematology analyzer. TP #7 (hire date 06/23/17) TP#8 (hire date 09/15/17) TP#10 (hire date 10/01/17) TP#13 (hire date 07/01/18) TP#15 (hire date 07/01/18) 2. An interview with the technical consultant on 11/26/18 at 0940 hours in the breakroom confirmed the above findings. key: CMS - Centers for Medicaid and Medicare Services TP - testing personnel

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policies, 2016 through 2018 personnel records, and confirmed in interview, the technical consultant failed to perform semi-annual competency for 4 of 4 testing person (TP) during the first year of testing patient specimens for the moderately complex testing performed on the Sysmex Poch-100i hematology analyzer. (TP#3, TP#4, TP# 8, TP#10) Findings were: 1. Review of the laboratory policy Competency Evaluation (GEN-04, implemented 09/15/16) revealed "Evaluation and documentation of the performance of laboratory testing personnel will be done upon completion of departmental training and at 6 months for all new employees including point of care personnel." 2. Review of the 2016 through 2018 personnel records revealed 4 of 4 testing person (TP#3, hire date: 10/03/16; TP#4, hire date: 10/03/16; TP#8, hire date: 09/15/17; TP#10, hire date 10/01/17) with no documentation of the semi-annual competency during the first year of testing patient specimens. 3. An interview with the technical consultant on 11/26/18 at 1530 hours in the break room confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS-209, review of the

laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education for 9 of 9 testing personnel. Refer to D6065

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education to qualify 9 of 9 testing personnel for moderately complex testing for CBC (complete blood count) on the Sysmex Poch-100i hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of education for 9 of 9 testing personnel (TP#2, TP#3, TP#4, TP#5, TP#7, TP#8, TP#10, TP#13, and TP#15) 2. An interview with the technical consultant on 11/26/18 at 0940 hours in the break room confirmed the above findings. CMS - Centers of Medicare and Medicaid Services