

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0986052	<b>(X3) Date Survey Completed</b>  11/19/2020
<b>Name of Provider or Supplier</b>  Dr Elvin R Garcia Md Pa	<b>Street Address, City, State</b>  811 E Fern Ave Suite 1, Mcallen, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5300 - 42 C.F.R. 493.1240 Condition: Pre-Analytic Systems D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity NOTE: To abate the immediate jeopardy, the facility provided a letter stating they would follow manufacturer's instructions. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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 Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 3 of 9 attestation statements and testing personnel signing 2 of 9 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from</p>

2019 (Chemistry Core events 1, 2 and 3) 2020 (Chemistry Core events 1, 2, and 3, and Immunology/Immunoematology events 1, 2, and 3) revealed the laboratory failed to have documentation of the laboratory director signing 3 of 9 attestation statements. The attestation statements without laboratory director signature were: 2019 Core Chemistry event 1 2019 Core Chemistry event 2 2020 Immunology /Immunoematology event 2 2. Further review of the laboratory's American Proficiency Institute's proficiency testing records from 2019 (Chemistry Core events 1, 2 and 3) 2020 (Chemistry Core events 1, 2, and 3, and Immunology /Immunoematology events 1, 2, and 3) revealed the laboratory failed to have documentation of testing personnel signing 2 of 9 attestation statements. The attestation statements without testing personnel signature were: 2019 Core Chemistry event 2 2020 Immunology/Immunoematology event 2 3. The laboratory was asked to provide documentation of the missing signatures. No documentation was provided. 4. An interview with the technical consultant on 11/19/2020 at 1015 hours in the break room - after his review of the records- confirmed the findings.

**D2121**

**HEMATOLOGY**

CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2018 for Hematology/Coagulation and staff interview, it was revealed the laboratory failed to achieve a successful score of at least 80% for White Blood Cell differential on 1 of 3 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2018 (Hematology/Coagulation events 1, 2 and 3) revealed the laboratory failed to achieve an successful score of at least 80% for White Blood Cell differential on 1 of 3 events. 2018 event 1 WBC differential score: 40% 2. An interview with the technical consultant on 11/19/2020 at 1015 hours in the break room - after his review of the records- confirmed the findings. Key WBC - white blood cell

**D5213**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2019 and 2020, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results which were returned by the proficiency testing agency as 'not graded'. The findings were: 1. A review of the laboratory's American Proficiency Institutes proficiency testing records from 2019 (Immunology/Immunoematology events 1,2, and 3, and 2020 Chemistry - Miscellaneous events 1, 2, and 3) revealed the following results which were returned as "not graded" by the proficiency testing agency: a) 2019 Immunology /Immunoematology event 1 Anti-RNP/Sm sample: ANA-02 b) 2019 Immunology

	<p>/Immunochemistry event 3 Anti-ds DNA sample: ANA-15 Anti-RNP/Sm sample: ANA-15 c) 2020 Chemistry - Miscellaneous event 1 25-OH Vitamin D sample: IAS-03 2. The laboratory was asked to provide documentation of evaluating the identified results. No documentation was provided. 3. An interview with the technical consultant on 11/19/2020 at 1015 hours in the break room revealed he had indicated the results had not been graded on his monthly quality assurance reports however the laboratory had not evaluated the results. This confirmed the findings.</p>
<p><b>D5215</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2020 and staff interview, it was revealed the laboratory failed to participate in 1 of 3 events for Immunology/Immunochemistry. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2020 (Immunology/Immunochemistry events 1, 2, and 3) revealed the laboratory failed to participate in 1 of 3 events. The laboratory did not submit results for: 2020 Immunology/Immunochemistry event 2 2. The laboratory was asked to provide documentation of participating in the event or of evaluating the laboratory's results after the submission deadline. No documentation was provided. 3. An interview with the technical consultant on 11/19/2020 at 1015 hours in the break room - after his review of the records- confirmed the findings.</p>
<p><b>D5221</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2020 and staff interview, it was revealed the laboratory failed to have documentation of the review of 3 of 9 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2020 (Immunology/Immunochemistry events 1, 2 and 3, Hematology/Coagulation events 1, 2, and 3, and Chemistry - Core events 1, 2, and 3) revealed the laboratory failed to have documentation of the review of results for 3 of the 9 events. The events without documentation of review were: 2020 Immunology/Immunochemistry event 2 2020 Hematology/Coagulation event 2 2020 Chemistry - Core event 2 2. The laboratory was asked to provide documentation of the review of results. No documentation was provided. 3. An interview with the technical consultant on 11/19/2020 at 1015 hours in the break room - after his review of the records - confirmed the findings.</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p>

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 the laboratory's records, review of the laboratory's American Proficiency Institute's proficiency testing records and staff interview, it was revealed the laboratory's quality assessment plan failed to identify when the proficiency testing agency did not evaluate the laboratory's results to other laboratories using the same analyzer. The findings were: 1. A review of the laboratory's records revealed the laboratory replaced its hematology analyzer in May 2018. The laboratory installed a Sysmex XP-300 analyzer. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2018 revealed the laboratory failed to indicate the instrument in use to the proficiency testing agency for first event after the change to the new analyzer (2018 event 2). As a result, the proficiency testing agency graded the laboratory's responses against all responses for hematology and not against those specifically for the Sysmex XP 300 analyzer. 3. The laboratory's quality assessment failed to identify that the laboratory's proficiency results were not evaluated against its peer group. 4. An interview with the technical consultant on 11/19 /2020 at 1015 hours in the break room revealed he was unaware that the results were not evaluated against the results of other laboratories using the Sysmex XP-300 analyzer. This confirmed the findings.

**D5300**

**PREANALYTIC SYSTEMS**  
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of the manufacturer's instructions, review of the laboratory's records and staff interview, it was revealed the laboratory failed to following manufacturer's instructions for the proper storage of specimens prior to testing (refer to D5311).

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
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:

Based on review of the manufacturer's instructions for the Immunodot Autoimmunity Screening Panel 1, the manufacturer's instructions for the NanoEnTek FREND Vitamin D assay, the manufacturer's instructions for the NanoEnTek FREND TSH assay, review of patient test records, review of the laboratory's freezer temperature records, and staff interview, it was revealed the laboratory failed to follow manufacturer's instructions for the proper storage of samples prior to testing. The findings were: A) Immunodot Autoimmunity Screening Panel 1 1. A review of the manufacturer's instructions for the Immunodot Autoimmunity Screening Panel 1 (110-0105, effective date: June 24, 2019) under the section titled "Specimen Collection and Handling" revealed: "Serum or heparinized whole blood may be stored at 2 - 8C for up to five days. Serum may be frozen below -20C for extended periods." 2. A random sampling of patient test records from February 2020, March 2020 and May 2020 revealed the following patients whose samples were tested more than 5 days after collection and thus were required to be stored at -20C or colder: a) Test Date: 02/03/2020 Patient ID: BARROS0001 Collection date: 01/16/2020 elapsed time: 18 days Patient ID: CANBEL0001 Collection date: 01/17/2020 elapsed time: 17 days Patient ID: GAROTI0001 Collection date: 01/23/2020 elapsed time: 11 days Patient ID: CASJUL0005 Collection date: 01/23/2020 elapsed time: 11 days Patient ID: VERSAN0003 Collection date: 01/23/2020 elapsed time: 11 days Patient ID: GALSUS0001 Collection date: 01/23/2020 elapsed time: 11 days Patient ID: GUINOR0002 Collection date: 01/23/2020 elapsed time: 11 days Patient ID: GUEANA001 Collection date: 01/24/2020 elapsed time: 10 day Patient ID: TREMAR0033 Collection date: 01/28/2020 elapsed time: 6 days b) Test date: 02/07/2020 Patient ID: RANJOS0001 Collection date: 01/29/2020 elapsed time: 9 days Patient ID: RODMAR0047 Collection date: 01/30/2020 elapsed time: 8 days Patient ID: SALQUE0001 Collection date: 01/31/2020 elapsed time: 7 days c) Test date: 03/05/2020 Patient ID: MCCMAR0004 Collection date: 02/21/2020 elapsed time: 13 days Patient ID: RODARA0002 Collection date: 02/24/2020 elapsed time: 10 days Patient ID: MORNIN0002 Collection date: 02/24/2020 elapsed time: 10 days Patient ID: GARMAR0067 Collection date: 02/24/2020 elapsed time: 10 days Patient ID: GUHJUD0001 Collection date: 02/24/2020 elapsed time: 10 days Patient ID: PRUADA0001 Collection date: 02/25/2020 elapsed time: 9 days Patient ID: VELZOL0001 Collection date: 02/25/2020 elapsed time: 9 days Patient ID: NAVASAN0002 Collection date: 02/25/2020 elapsed time: 9 days Patient ID: SANNOE0004 Collection date: 02/25/2020 elapsed time: 9 days Patient ID: ZEMPAT0001 Collection date: 02/26/2020 elapsed time: 8 days Patient ID: ELANT0002 Collection date: 02/26/2020 elapsed time: 8 days Patient ID: PALDIA0001 Collection date: 02/26/2020 elapsed time: 8 days Patient ID: BLAMIR0001 Collection date: 02/27/2020 elapsed time 7 days c) Test date: 03/19/2020 Patient ID: DELJES0001 Collection date: 03/04/2020 elapsed time: 15 days Patient ID: STIDJ00001 Collection date: 03/05/2020 elapsed time: 14 days Patient ID: GARIRM0008 Collection date: 03/05/2020 elapsed time: 14 days Patient ID: SOTMAR0017 Collection date: 03/05/2020 elapsed time: 14 days Patient ID: LOPGRA0004 Collection date: 03/06/2020 elapsed time: 13 days Patient ID: MARSAN0016 Collection date: 03/09/2020 elapsed time: 10 days Patient ID: BARJUA0006 Collection date: 03/10/2020 elapsed time: 9 days Patient ID: GARNIN0001 Collection date: 03/10/2020 elapsed time: 9 days Patient ID: COCMAR0001 Collection date: 03/11/2020 elapsed time: 8 days Patient ID: GREOLG0001 Collection date: 03/11/2020 elapsed time: 8 days Patient ID: GARANG0001 Collection date: 03/13/2020 elapsed time: 6 days d) Test date: 05/19/2020 Patient ID: CASVER0001 Collection date: 05/04/2020 elapsed time: 15 days Patient ID: SAEROS0010 Collection date: 05/04/2020 elapsed time: 15 days Patient

ID: RODPAU0005 Collection date: 05/05/2020 elapsed time: 14 days Patient ID: RYEMAN0004 Collection date: 05/05/2020 elapsed time: 14 days Patient ID: LOPFLO0001 Collection date: 05/06/2020 elapsed time: 13 days Patient ID: UREOLG0001 Collection date: 05/07/2020 elapsed time: 12 days Patient ID: COLKAT0001 Collection date: 05/08/2020 elapsed time: 11 days 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 11/19/2020 at 1500 hours in the laboratory revealed samples for testing using the Immunodot Autoimmunity Screening Panel 1 - if not tested the day of collection - would be poured off into storage tubes and placed in the freezer above the refrigerator until testing could be performed. 4. A review of the laboratory's documented freezer temperatures revealed the following: a) February 2020 20 of 20 days the documented freezer temperature was warmer than -20C b) March 2020 22 of 22 days the documented freezer temperature was warmer than -20C c) May 2020 21 of 21 days the documented freezer temperature was warmer than -20C Note: the laboratory's temperature log states temperatures were recorded in Fahrenheit (F) however, surveyor observation on 11/19/2020 at 1430 in the laboratory revealed the thermometer was actually monitoring the temperature in Celsius (C). The technical consultant confirmed this. Thus, the freezer never attained a temperature cold enough to store the samples as required by manufacturer's instructions. 5. An interview with the technical consultant on 11/19/2020 at 1515 hours in the office - after his review of the records - confirmed the findings. B) NanoEnTek FREND Vitamin D 1. A review of the manufacturer's instructions for the NanoEnTek FREND Vitamin D assay (NESPI-FVAP-002EN(V.0.0)) under the section titled "Specimen collection and handling" revealed: "Samples may be stored at 36-46F (2 - 8C) for up to 6 hours prior to analysis. If the analysis is scheduled to be done at some later time, the serum or plasma sample should be separated from the red cells and stored frozen at -4F (-20C) or below for future use." 2. 2. A random sampling of patient test records from November 2020 revealed the following patients whose samples were tested more than 6 hours after collection and thus were required to be stored at -20C or colder: a) Test date: 11/02/2020 Patient ID: CANMAR0057 Collection date: 10/05/2020 elapsed time: 28 days Patient ID: ELIGRA0001 Collection date: 10/05/2020 elapsed time: 28 days Patient ID: GOMEUN0001 Collection date: 10/05/2020 elapsed time: 28 days Patient ID: Leamar0007 Collection date: 10/05/2020 elapsed time: 28 days Patient ID: VILMIR0003 Collection date: 10/06/2020 elapsed time: 27 days Patient ID: LOEJES0001 Collection date: 10/08/2020 elapsed time: 25 days Patient ID: GUESAN0004 Collection date: 10/08/2020 elapsed time: 25 days Patient ID: TALDEB0001 Collection date: 10/12/2020 elapsed time: 21 days Patient ID: ZAMPAT0001 Collection date: 10/12/2020 elapsed time: 21 days Patient ID: LOPROS0007 Collection date: 10/14/2020 elapsed time: 19 days Patient ID: VALORA0001 Collection date: 10/15/2020 elapsed time: 18 days Patient ID: PERFRA0002 Collection date: 10/15/2020 elapsed time: 18 days b) Test date: 11/10/2020 Patient ID: LOPROS0012 Collection date: 10/16/2020 elapsed time: 25 days Patient ID: DIACRI0001 Collection date: 10/19/2020 elapsed time: 22 days Patient ID: LOZELI0001 Collection date: 10/20/2020 elapsed time: 21 days Patient ID: HERVIC0002 Collection date: 10/21/2020 elapsed time: 20 days Patient ID: MARJUL0007 Collection date: 10/21/2020 elapsed time: 20 days Patient ID: rodgra0003 Collection date: 10/21/2020 elapsed time: 20 days Patient ID: MENANT0001 Collection date: 10/23/2020 elapsed time: 18 days Patient ID: RAMPAS0001 Collection date: 10/27/2020 elapsed time: 14 days Patient ID: VASALB0002 Collection date: 10/27/2020 elapsed time: 14 days 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 11/19/2020 at 1500 hours in the laboratory revealed samples for testing using the NanoEnTek FREND Vitamin D assay - if not tested the day of collection - would be poured off into storage

tubes and placed in the freezer above the refrigerator until testing could be performed.

4. A review of the laboratory's documented freezer temperatures from October 2020 and November 2020 (11/1/2020 to 11/10/2020) revealed the following: a) October 2020 22 of 22 days the documented freezer temperature was warmer than -20C b) November 1 to November 10, 2020 7 of 7 days the documented freezer temperature was warmer than -20C Note: the laboratory's temperature log states temperatures were recorded in Fahrenheit (F) however, surveyor observation on 11/19/2020 at 1430 in the laboratory revealed the thermometer was actually monitoring the temperature in Celsius (C). The technical consultant confirmed this. Thus, the freezer never attained a temperature cold enough to store the samples as required by manufacturer's instructions. 5. An interview with the technical consultant on 11/19/2020 at 1515 hours in the office - after his review of the records - confirmed the findings. C)

NanoEnTek FREND TSH assay 1. A review of the manufacturer's instructions for the NanoEnTek FREND TSH assay (NESPI-FRTS-001EN (V.1.1)) under the section titled "Specimen collection and handling" revealed: "Samples may be stored at 36-46F (2 - 8C) for up to 6 hours prior to analysis. If the analysis is scheduled to be done at some later time, the serum or plasma sample should be separated from the red cells and stored frozen at -4F (-20C) or below for future use." 2. A random sampling of patient test records from June 2020 revealed the following patients whose samples were tested more than 6 hours after collection and thus were required to be stored at -20C or colder: a) Test date: 06/11/2020 Specimen ID: BOTANT0001 Collection date: 01/08/2020 elapsed time: 155 days Specimen ID: GONANG0006 Collection date: 03/02/2020 elapsed time: 101 days Specimen ID: REYMAN0004 Collection date: 05/05/2020 elapsed time: 37 days 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 11/19/2020 at 1500 hours in the laboratory revealed samples for testing using the NanoEnTek FREND TSH assay - if not tested the day of collection - would be poured off into storage tubes and placed in the freezer above the refrigerator until testing could be performed. 4. A review of the laboratory's documented freezer temperatures from January 2020 to June 2020 (06/01/2020 to 06/11/2020) revealed the following: a) January 2020 22 of 22 days the documented freezer temperature was warmer than -20C b) February 2020 20 of 20 days the documented freezer temperature was warmer than -20C c) March 2020 22 of 22 days the documented freezer temperature was warmer than -20C d) April 2020 23 of 23 days the documented freezer temperature was warmer than -20C e) May 2020 21 of 21 days the documented freezer temperature was warmer than -20C f) June 1 -11, 2020 6 of 8 days the documented freezer temperature was warmer than -20C Note: the laboratory's temperature log states temperatures were recorded in Fahrenheit (F) however, surveyor observation on 11/19/2020 at 1430 in the laboratory revealed the thermometer was actually monitoring the temperature in Celsius (C). The technical consultant confirmed this. Thus, the freezer never attained a temperature cold enough to store the samples as required by manufacturer's instructions. 5. An interview with the technical consultant on 11/19/2020 at 1515 hours in the office - after his review of the records - confirmed the findings.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

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

This CONDITION is not met as evidenced by:

Based on review of the laboratory's records and staff interview, it was revealed the laboratory failed to monitor, evaluate and correct problems in analytic systems. The findings were: 1. The laboratory failed to have a policy to address flags on the Sysmex XP-300 hematology analyzer (refer to D5403). 2. The laboratory failed to ensure expired controls were not used (refer to D5417). 3. The laboratory failed to ensure verification studies were complete (refer to D5421). 4. The laboratory failed to ensure all required maintenance was performed (refer to D5429). 5. The laboratory failed to ensure positive and negative controls were tested each day of patient testing for qualitative assays (refer to D5449).

**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 manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of the laboratory's policies, review of patient test records, and staff interview, it was revealed the laboratory failed to have a policy to resolve flags on CBC (complete blood count) results. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code no. AU553517, Date of Last Revision: July 2017) under the section titled "Technical Information" revealed: "Analysis of histogram allows use of the flagging system that suggests sample error or instrument error." 2. The manufacturer's instructions also included the description of the following WBC (white blood cell) histogram flags: WL: Relative frequency for LOWER discriminator (LD) exceeds the range. Probable cause is inclusion of numerous platelets, large platelets, and etc. T1: Lower TROUGH Discriminator, that distinguishes lymphocytes and mixed cells, cannot be not determined. T2: High TROUGH Discriminator, that distinguishes mixed cells and neutrophils, cannot be not determined. F1: Small cell histogram error. Relative frequency for T1 exceeds the range. F2: Middle cell histogram error. Relative frequency for T1 or T2 exceeds the range. F3: Large cell histogram error. Relative frequency for T2 exceeds the range. WU: Relative frequency for UPPER

discriminator (UD) exceeds the range. Applicable case is that in which considerable leukocyte aggregation or numerous abnormal blood cells are present. AG: The particle count equal to or less than the LD exceed a prescribed range. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. Therefore, this flag is added to the PLT parameter. Note: The manufacturer's instructions did not state the steps to take to resolve the identified flags. 3. A review of the laboratory's policies revealed the facility did not have a policy to address flags on CBC results and the steps to take to resolve them prior to reporting out patient results to ensure accurate and reliable results. 4. A sampling of instrument printouts of patient results from November 13, 2020 to November 18, 2020 revealed the following patient results with flags: a) Test date: 11/13/2020 Specimen ID: 46253 Flag: AG b) Test date: 11/16/2020 Specimen ID: 46257 Flag: AG Specimen ID: 46260 Flag: AG Specimen ID: 46266 Flag: AG c) Test date: 11/17/2020 Specimen ID: 46270 Flag: AG Specimen ID: 46272 Flag: AG Specimen ID: 46781 Flag: AG d) Test date: 11/18/2020 Specimen ID: 46284 Flag: AG Specimen ID: 46285 Flag: AG Specimen ID: 46291 Flag: AG 5. An interview with the technical consultant on 11/19/2020 at 1115 hours in the break room - after his review of the records- confirmed the laboratory did not have a policy to address flags on CBC results.

**D5417**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on review of the manufacturer's instructions for the Sysmex Eightcheck 3WP x-tra controls, surveyor observation of control material currently in use in the laboratory, review of patient test records, and staff interview, it was revealed the laboratory failed to ensure control material was not used past its expiration. The findings were: 1. A review of the manufacturer's instructions for the Sysmex Eightcheck 3WP x-tra controls (AQ578643C) under the section titled "Storage and shelf lif after first opening" revealed: "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2 - 8C after being recapped." 2. Surveyor observation on 11/19/2020 at 1340 hours in the laboratory revealed the controls currently in use were labeled with an opened date of 10/16/2020. Thus the controls had expired on 10/30/2020. There were no other opened controls in the refrigerator. 3. A review of patient test records from 10/31/2020 to 11/19/2020 revealed the expired control material had been used for 15 days of patient testing. A total of 227 patients were tested on days when the controls were expired (see patient alias list). 4. An interview with the technical consultant on 11/19/2020 at 1340 hours in the laboratory - after his review of the records and controls in use- confirmed the 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:

Based on review of the laboratory's verification studies for the Sysmex XP-300 hematology analyzer, review of patient results, and staff interview, it was revealed the laboratory failed to have documentation of performing complete studies. The findings were: 1. A review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer in April 2018 revealed the laboratory failed to have documentation of precision studies and of verifying patient normal ranges. 2. A review of patient results revealed the laboratory was utilizing the following normal ranges for both male and female patients: WBC: 4.2-10.0 RBC: 4.5-6.30 HGB: 14.0-18.0 HCT: 41.0 - 51.0 MCV: 80.0 -94.0 MCH: 27.0-34.0 MCHC: 31.5-36.0 RDW: 11.0-14.6 PLT: 140-440 MPV: 6.8-10.6 LY#: 1.2-3.2 LY%: 22.4-43.6 MID#: 0.1-1.0 MID%: 2.0-10.0 GRAN%: 48.9-69.9 GRAN#: 1.5-6.7 3. An interview with the technical consultant on 11/19/2020 at 1130 hours in the laboratory - after is review of the records- 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 the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of maintenance records from May 2018 to November 2020 (as of the day of the survey) and staff interview, it was revealed the laboratory failed to have documentation of performing all required maintenance. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Revised March 2017) under the section titled "12.1 Maintenance schedule" revealed: Daily: Clean TD chambers and diluted sample lines Check trap chamber level and discard Weekly: Clean SRV tray Every Month: Clean TD Clean waste chamber Every 3 months Clean SRV 2. A review of the laboratory's Sysmex XP-300 analyzer's maintenance records from May 2018 to November 2020 (as of the day of the survey) revealed the laboratory failed to have documentation of the following: a) Weekly missing 4 of 5 weeks in June 2018 missing 1 of 4 weeks in August 2018 missing 1 of 4 weeks in October 2018 missing 1 of 4 weeks in November 2018 missing 1 of 4 weeks in January 2019 missing 2 of 5 weeks in February 2019 missing 2 of 5 weeks in March 2019 missing 1 of 5 weeks in May 2019 missing 1 of 4 weeks in June 2019 missing 1 of 5 weeks in August 2019 missing 1 of 5 weeks in October 2019 missing 1 of 4 weeks in November 2019 missing 2 of 4 weeks in December 2019 missing 1 of 5 weeks in January 2020 missing 1 of 4 weeks in April 2020 missing 1 of 4 weeks in May 2020 missing 1 of 5 weeks in June 2020 missing 1 of 5 weeks in July 2020 missing 1 of 2 weeks in August 2020 missing 1 of 5 weeks in October 2020 Note: Laboratory was closed for two weeks in August 2020 b) Monthly missing in June 2018 missing in December 2019 missing in August 2020 - cleaning transducers (TD) c) Every 3 months No documentation of this being performed from May 2018 to

October 2020 for a total of 10 events 3. An interview with the technical consultant on 11/19/2020 at 1230 hours in the manager's office - after his review of the records-confirmed the findings.

**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 the Immunodot Autoimmunity Screening Panel 1 test kit, a review of the laboratory's quality control records for the Immunodot Autoimmunity Screening Panel 1, and staff interview, it was revealed the laboratory failed to have documentation of testing positive and negative controls for 2 of 4 qualitative assays which were part of the panel. The findings were: 1. A review of the Immunodot Autoimmunity Screening Panel 1 test kit revealed the kit qualitatively screened for the following: Total ANA ds-DNA RNP/Sm SS A/B 2. A random sampling of the laboratory's quality control records for the Immunodot Autoimmunity Screening Panel from 02/03/2020, 02/21/2020, 03/05/2020, 03/19/2020, and 5/19/2020 revealed the laboratory failed to test negative controls for Total ANA and SS A/B. The documented control results were: positive control Total ANA + ds-DNA + RNP/Sm + SS A/B + negative control Total ANA + ds-DNA = RNP/Sm = SS A/B + 3. An interview with testing personnel number 3 (as listed on Form CMS 209) at 1515 hours in the laboratory revealed that the results documented were the results he always obtained when the ran the controls. This confirmed the findings. Key + - positive result = - negative result

**D5801**

**TEST REPORT**  
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of patient test records, review of patient test results, and staff interview, it was revealed the laboratory failed to ensure flagged results from the CBC analyzer transferred and were reported out through the laboratory's information system. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code no. AU553517, Date of Last Revision: July 2017) under the section titled "Technical Information" revealed: "Analysis of

histogram allows use of the flagging system that suggests sample error or instrument error." 2. A sampling of instrument printouts of patient results from November 13, 2020 to November 18, 2020 revealed the following patient results with flags: a) Test date: 11/13/2020 Specimen ID: 46253 Flag: AG b) Test date: 11/16/2020 Specimen ID: 46257 Flag: AG Specimen ID: 46260 Flag: AG Specimen ID: 46266 Flag: AG c) Test date: 11/17/2020 Specimen ID: 46270 Flag: AG Specimen ID: 46272 Flag: AG Specimen ID: 46781 Flag: AG d) Test date: 11/18/2020 Specimen ID: 46284 Flag: AG Specimen ID: 46285 Flag: AG Specimen ID: 46291 Flag: AG 3. A review of the patient reports for the identified samples revealed the reported values did not include the flags from the analyzer for all 10 patients. 4. An interview with the technical consultant on 11/19/2020 at 1115 hours in the break room - after his review of the records- confirmed the instrument flags did not transfer to the final reports.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

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

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The finding were: 1. The laboratory director failed to ensure verification studies were complete (refer to D6013). 2. The laboratory director failed to ensure the laboratory submitted proficiency testing results within the required timeframe (refer to D6017). 3. The laboratory director failed to ensure proficiency testing results were reviewed (refer to D6018). 4. The laboratory director failed to ensure a quality control plan was developed and followed (refer to D6020). 5. The laboratory director failed to ensure the quality assessment plan identified and corrected problems in general laboratory systems (refer to D6021). 6. The laboratory director failed to ensure flags on results were transferred to the laboratory's information system (refer to D6026).

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

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;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's verification records for the Sysmex XP-300 hematology analyzer and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete (refer to D5421).

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's American Proficiency Institute's proficiency testing results, and staff interview, it was revealed the laboratory director failed to ensure results were returned within the required timeframe (refer to D5215).

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's American Proficiency Institute's proficiency testing results and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5221).

**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 the laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was established and followed. The findings were: 1. The laboratory director failed to ensure expired controls were not used (refer to D5417). 2. The laboratory director failed to ensure positive and negative controls were tested for qualitative tests (refer to D5449).

**D6021**

**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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected problems in general laboratory systems (refer to D5291).

**D6026**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:  
Based on review of instrument printouts, review of patient results and staff interview, it was revealed the laboratory director failed to ensure flags on results were transferred to the laboratory's information system (refer to D5801).

**D6040**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(2)

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.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's verification records for the Sysmex XP-300 hematology analyzer and staff interview, it was revealed the technical consultant failed to ensure verification studies were complete (refer to D5421).

**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 the laboratory's quality control records and staff interview, it was revealed the technical consultant failed to ensure a quality control program was established and followed. The findings were: 1. The technical consultant failed to ensure expired controls were not used (refer to D5417). 2. The technical consultant failed to ensure positive and negative controls were tested for qualitative tests (refer to D5449).

**D6055**

**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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's test menu, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to reevaluate the competency of 2 of 3 testing personnel when testing methodology changed. The findings were: 1. A review of the laboratory's test menu revealed a new hematology analyzer was placed into use in May 2018. 2. A review of the laboratory's personnel records revealed the technical consultant failed to have assess the competency of 2 of 3 testing personnel prior to the performing testing on patient samples. Testing personnel number 2 trained on 05/24/2018 assessed on 08/27/2018 Testing personnel number 3 trained on 05/24/2018 assessed on 08/27/2018 3. An interview with the technical consultant on 11/19/2020 at 1045 hours in the conference room revealed that he was unaware of the need to assess the competency of testing personnel prior to testing patient samples. He stated the competencies performed were done as part of the regular annual evaluation. This confirmed the findings.