Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1077917	03/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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 condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were 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.
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 observations, review of laboratory policies and manufacturer's instructions, patient test results, and confirmed in interview, the laboratory failed to follow the lab policy when processing and testing CBC (complete blood count) specimens on the Sysmex XS 1000i hematology analyzer. Findings were: 1. Surveyor observations on 03/28/18 at 1050 hours in the laboratory revealed the testing person performed a CBC

	analysis on a short sample (volume less than one half of the tube). Patient ID 8556 2. Review of the laboratory policy Sysmex XS-1000i (HEM105, effective date 02/2016) revealed "required volume: optimal draw is a tube filled to capacity. The collection tube should be filled to a minimum of one-half for acceptable results." 3. Review of the manufacturer instructions XS Series Flagging Interpretation Guide (1269-LSS, Rev 1, September 2016) revealed "compromised samples such as those not properly collected, stored, transported, or containing clots may cause misleading results. Always use good laboratory practices for inspecting specimens for acceptability and verifying results." 4. Review of patient result for Patient ID 8556 revealed it was reported on 03/28/18 with Immature Gran flag. 5. An interview with the technical consultant on 03/28/18 at 1050 hours in the laboratory confirmed the above findings. She acknowledged that the specimen was a short sample and that the testing person should not have analyzed the specimen. This is a repeat deficiency from the 02/10 /2016 survey. key: Immature Gran - abnormal clustering in the region for immature granulocytes in the DIFF scattergram
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: A. Based on review of manufacturer's instructions, direct observation, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions in setting evidence based limits for quality control for CBC (complete blood count) analysis on the Sysmex XS1000i hematology analyzer. Findings were: 1. Review of the Sysmex Product Information Sysmex Evidence-Based Control Limits (Document No. 63-1100, 02/2014) revealed the laboratory "enter analyzer specific control limits from the table attached." Published Evidence Based Limits Parameter L1 L2 L3 RBC 5.0 4.0 4 HGB 6.0 4.3 4.2 HCT 6.0 5.1 5 MCV 4.9 4.3 4 MCH 5.6 4.5 4.3 MCHC 6.8 5.7 5.4 PLT 23.0 12.0 9.7 RDW-SD 7.1 7.3 8.1 RDW-CV 7.5 5.9 6.3 MPV 10.9 6.9 5.5 WBC 11.4 7.8 7.8 WBC-D 10.5 8.5 7.6 NEUT% 11.1 8.9 8.1 LYMPH% 12.1 9.1 7.7 MONO% 35.0 24.0 19.7 EO% 29.3 28.3 28.4 BASO% 34.9 31.1 31.1 NEUT# 15.1 12.4 11.1 LYPMH# 16.1 12.5 10.9 MONO# 36.5 25.5 21.0 EO# 31.2 29.6 29.6 BASO# 36.3 32.9 32 2. Direct Observations of the laboratory quality control limits setting on the Sysmex XS1000i hematology analyzer revealed documentation that the laboratory did not use the above evidence based limits. Random review of laboratory records from 2016 and 2017 revealed the laboratory used 100% limits for all analytes. 3. Interview with the technical consultant on 03/28 /18 at 1020 hours in the office confirmed the above findings. She was unaware the laboratory was using incorrect limits. B. Based on a review of the manufacturer's instructions, laboratory policy, patient test records, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions to ensure system flags were verified prior to reporting patient results from the Sysmex XS 1000i hematology analyzer. Findings were: 1. A review of the Sysmex XS-Series Automated Hematology Analyzer Flagging Interpretation Guide (document number 1269-LSS, September 2016): "Any asterisk next to a parameter indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting" "WBC Abn Scattergram - Verify WBC and differential results

according to your laboratory's policy. Possible actions may include: Repeating the sample, performing a manual differential. Asterisk next to results: Verify WBC and differential results according to your laboratory's policy. Possible actions may include scanning the slide for abnormal cells or platelet clumping and to estimate the WBC count; perform a manual differential if abnormal cells are observed. If no abnormalities are found when reviewing the smear and the WBC estimate matches the analyzer reported WBC, the results with asterisks may be reported." "Blasts? - Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of: blasts, immature granulocytes, atypical immature lymphocytes, other abnormal cells. If no abnormalities are found, the results with the asterisk may be reported. If dashes are in place of numeric data, verify differential results according to your laboratory's policy. Possible action may include: repeating the sample, performing a manual differential." "Immature Gran? - Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of immature granulocytes, band cells in increased numbers, toxic granulation or vacuolation of neutrophils, other abnormal cells. Report any abnormal cells according to your laboratory protocol. If no abnormalities are found when reviewing the smear, the results with asterisks may be reported." "NRBC? - Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of NRBCs or other abnormal cells. Report any NRBCs or abnormal cells according to your laboratory protocol...If no abnormalities are found when reviewing the smear, the results with asterisks may be reported." "PLT Abn Distribution - Suggested Action Steps: Review results according to your laboratory protocol. Possible actions include: scan the peripheral smear to estimate the platelet count and review for the presence of abnormal RBC or PLT morphology such as large or giant platelets; small platelets; platelet clumps; fragmented RBCs; microcytic RBCs, parasites. If abnormal RBC, PLT or other morphology is noted, report according to your local laboratory protocol. If platelet estimate confirms accuracy of analyzer count, it may be reported. If platelet estimate does not confirm accuracy of analyzer count, confirm with an alternate method such as manual platelet count according to your local laboratory protocol." "PLT Clumps - Suggested Action Steps: Follow your local laboratory protocol. Possible actions may include: checking the sample for the presence of clots; scanning the peripheral smear, especially the feathered edge for the presence of abnormal morphology including: fibrin strands, platelet clumps. If any of the above are present, verify the WBC and PLT by a manual slide estimate. If the WBC and PLT estimates match the analyzer counts, report the results according to your local laboratory protocol. If the estimates do not match the analyzer counts, review the feathered edge and sides of the peripheral smear is suggested as platelet clumps and fibrin strand may migrate to this area during smear preparation." "Atypical Lymph - Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of: atypical or variant lymphocytes; abnormal or atypical monocytes; immature lymphocytes, such as seen in ALL or CLL; immature monocytes; smudge cells; other abnormal cells. Report any abnormal cells according to your laboratory protocol. If no abnormalities are found, the results with the asterisk may be reported. If dashes are in place of numeric data, verify differential results according to your laboratory policy. Possible actions may include: repeating the sample; performing a manual differential." "RBC Abn Distribution - Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of abnormal RBC morphology such as: increased anisocytosis, multiple RBC populations, fragmented RBCs poikilocytosis, rouleaux or RBC agglutination. Report any abnormal RBC morphology according to your

laboratory protocol. If no abnormalities are found, the results with the asterisk may be reported. If dashes are in place of numeric data, verify differential results according to your laboratory policy. Possible actions may include: repeating the sample or reporting RBC morphology from smear review." "Dimorphic Population - Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of abnormal RBC morphology such as increased anisocytosis, multiple RBC populations, fragmented RBC poikilocytosis, rouleaux or RBC agglutination. Report any abnormal RBC morphology according to your laboratory protocol. If no abnormalities are found, the results with the asterisk may be reported. If dashes are in place of numeric data, verify differential results according to your laboratory policy. Possible actions may include: repeating the sample or reporting RBC morphology from smear review." "Left shift? - When bands are present, they are included in the neutrophil population. Suggested Action Steps: Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of: band cells in increased numbers; toxic granulation or vacuolization of neutrophils; other abnormal cells. Report any abnormal cells according to your laboratory protocol. If no abnormalities are found, the results with the asterisk may be reported. If dashes are in place of numeric data, verify differential results according to your laboratory policy. Possible actions may include: repeating the sample; performing a manual differential." 2. A review of the laboratory policy Sysmex XS-1000i Flagging Interpretations (HEM100, effective date of 12/2017) revealed "reporting procedure when messages/flags are present: "1) When messages or flags are present on a patient report, the testing personnel should confirm that the specimen was drawn, processed, and tested according to policies and procedures. 2) Testing personnel should also confirm the instrumentation is functioning within established guidelines. 3) Results are reported to the Medical director or physician. 4) The report printout is initialed by the testing personnel. By initialing the report, testing personnel are acknowledging that steps 1-3 have been verified and or performed. 5) The medical director or physician must review all flags, assess and correlate the results with the patient's medical records and clinical symptoms. Any further documentation will be made in the patient's medical records." 4. A random review of instrument printouts and final test reports from December 2017 to March 2018 revealed 12 of 40 patient samples reported with 1 or more of the above flags. 3/15/18 Patient flags 6145 WBC Abn Scattergram, Blasts? Immature Gran? NRBC? 9120 PLT Abn Distribution 3/13/18 Patient flags 8187 Immature Gran? NRBC? PLT Abn Distribution, PLT Clumps 8856 Atypical Lympho 4215 WBC Abn Scattergram, Immature Gran 2/20/18 Patient flags 2214 Immature Gran? RBC Abn Distribution, Dimorphic Population, 4740 PLT Abn Distribution, PLT Clumps 2/13 /18 Patient flags 8187 WBC Abn Scattergram, Immature Gran, NRBC, RBC Abn Distribution, PLT Abn Distribution, PLT clumps 01/15/18 Patient flags 7442 WBC Abn Scattergram, Left shift? NRBC? 12/27/17 2214 RBC Abn Distribution, Dimorphic Population, 12/18/17 Patient flags 7442 Immature Gran? left shift? 12/14 /17 Patient flags 8625 PLT Abn Distribution, 3. The laboratory was asked to provide documentation of the laboratory methods to review flags prior to reporting results that include performing a manual differential; scanning the peripheral smear for abnormal cells; and/or checking the sample for the presence of clots. No documentation was provided. 4. An interview with the technical consultant on 03/28/18 at 1040 hours in the office confirmed the above findings. An interview with the lab director on 03/28 /18 at 1140 hours in the office stated that she is a hematology specialist. She knows when a pathology review should be performed. key: CBC - complete blood count WBC Abn Scattergram - generated whenever clustering in the DIFF scattergram is abnormal. Blasts? - indicates that the analyzer has detected abnormal clustering in the region for blasts and abnormal lymphocytes in the DIFF scattergram. Immature Gran?

	- analyzer has detected abnormal clustering in the region for immature granulocytes in the DIFF scattergram. NRBC? - generated when clustering is detected in the NRBC area between the lymphocytes and the RBC ghosts on the DIFF scattergram. PLT Abn Distribution - generated by calculation and size comparison of certain PLT items. PLT Clumps - determined by abnormal clustering in the DIFF scattergrams. Atypical Lymph - indicates that the analyzer has detected significant clustering in the region for atypical lymphocytes that is is located in the upper left lymphocytes region on the DIFF scattergram. RBC Abn Distribution - generated when the histogram pattern from the RBC channel is abnormal. Suggested Action Steps: Review results according to your laboratory protocol. Dimorphic Population - generated when there are multiple peaks in the RBC histogram pattern. Left shift? - indicates that the analyzer has detected abnormal clustering in the region for left shift (bands) in the DIFF scattergram. When bands are present, they are included in the neutrophil population.
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 quality control records, laboratory patient test records, and confirmed in interview, the laboratory failed to establish quality control procedures to detect immediate errors for CBC (complete blood count) analysis on the Sysmex XS1000i hematology analyzer. Findings were: 1. Review of the laboratory quality control limits setting on the Sysmex XS1000i hematology analyzer revealed documentation that the laboratory did not use the evidence based limits. Review of the control limits set on the Sysmex XS1000I revealed the control limits were set at 100% for all analytes. Cross refer to D5411. 2. Random review of quality control records from 12/2017 to 03/2018 revealed 2 of 30 days when quality control was documented outside of the Sysmex e-Check (XS) published expected range (350519 Rev. 4 11/6 /12 Mar 18). 3/13/18 QC 80160804 exp 06/03/18 PLT lab result 41 expected range 43 - 77 03/15/18 QC 80160805 exp 06/03/18 WBC lab result 7.40 expected range 6.17 - 7.39 3. Review of patient records revealed the laboratory performed patient testing on the above dates when quality control failed. 3/13/18 8187 8856 4215 03/15/18 2036 9069 6145 3535 9120 4. An interview with the technical consultant on 03/28/18 at 1020 hours in the office confirmed the above findings. She acknowledged that since the limits were set at 100% the lower limit was set at 0. The instrument did not flag any quality control that was outside the expected range and the testing personnel did not verify the results with the quality control insert.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment records and laboratory procedures, the laboratory's quality assessment policies failed to monitor assess and correct problems in analytic systems. Findings were: 1. The laboratory failed to follow its procedure and ensure system flags were verified prior to reporting patient results from the Sysmex XS 1000i hematology analyzer. Refer to D5403 2. The laboratory failed to follow the manufacturer's instructions in setting evidence based limits for quality control for CBC (complete blood count) analysis on the Sysmex XS1000i hematology analyzer. Refer to D5411 3. The laboratory failed to establish quality control procedures to detect immediate errors for CBC (complete blood count) analysis on the Sysmex XS1000i hematology analyzer. Refer to D5441
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observations, review of laboratory policies and manufacturer's instructions, patient test results, and confirmed in interview, the laboratory director failed to ensure the testing personnel follow the lab policy when processing and testing CBC (complete blood count) specimens on the Sysmex XS 1000i hematology analyzer. Refer to D6068
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 quality control records, review of laboratory procedures, the technical consultant failed to establish a quality control program for the Sysmex XS 1000i hematology analyzer. Refer to D5403, D5411, D5441
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 observations, review of laboratory policies and manufacturer's instructions, patient test results, and confirmed in interview, the laboratory failed to have testing personnel who could process and test CBC (complete blood count) specimens on the Sysmex XS 1000i hematology analyzer. Refer to D6068
D6068	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425 The testing personnel are responsible for specimen processing, test performance, and for reporting test results. This STANDARD is not met as evidenced by: Based on observations, review of laboratory policies and manufacturer's instructions, patient test results, and confirmed in interview, the testing personnel failed to follow the lab policy when processing and testing CBC (complete blood count) specimens on the Sysmex XS 1000i hematology analyzer. Findings were: 1. Surveyor observations on 03/28/18 at 1050 hours in the laboratory revealed the testing person performed a CBC analysis on a short sample (volume less than one half of the tube). Refer to D5311