Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1025956	04/17/2018
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. 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. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the 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.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute's (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to test proficiency testing samples the same number of times it tests patient samples. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing Policy" under, "Proficiency Testing Policy and Procedure" stated, "3. Handle vial test in same manner as patient specimens are handled." 2. Review of the laboratory's policy titled, "Protocol for Flags" stated, "2. Sample results with the flag 1, 2, 3, 4, M in WBC differential will be reanalyzed from same specimen ..." 3. Review of the laboratory's API proficiency testing records from 2016 (event 2 and 3) and 2017 (events 1, 2, and 3) revealed the following specimens met the

	laboratory's repeat criteria. The laboratory did not test the proficiency testing sample the same number of times it would routinely test a patient: 2017 (event 1) Date: 03-15-2017 ID: HEM-03 Flag: * (not repeated) 2017 (event 1) Date: 03-15-2017 ID: HEM-04 Flag: * (not repeated) 2017 (event 1) Date: 03-15-2017 ID: HEM-05 Flag: * (not repeated) 2017 (event 2) Date: 07-19-2017 ID: HEM-07 Flag: * (not repeated) 2017 (event 3) Date: 11-16-2017 ID: HEM-11 Flag: * (not repeated) 2017 (event 3) Date: 11-16-2017 ID: HEM-13 Flag: * (not repeated) 2017 (event 3) Date: 11-16-2017 ID: HEM-14 Flag: * (not repeated) 2016 (event 2) Date: 07-21-2016 ID: HEM-06 Flag: * (not repeated) 2016 (event 2) Date: 07-21-2016 ID: HEM-07 Flag: * (not repeated) 2016 (event 2) Date: 07-21-2016 ID: HEM-08 Flag: * (not repeated) 2016 (event 3) Date: 11-09-2016 ID: HEM-13 Flag: * (not repeated) 2016 (event 3) Date: 11-09-2016 ID: HEM-14 Flag: * (not repeated) 4. The laboratory was asked to provide documentation of testing proficiency testing samples the same number of times as it tested patient samples. No documentation was provided. 5. An interview with testing personnel number one as listed on Form CMS-209 on 04/17/2018 at 1045 hours in the break room confirmed the findings,. Key: WBC - white blood cell CMS - Centers for Medicare and Medicaid Services
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Beckman Coulter AcT Diff 2 hematology analyzer, review of the laboratory's policies, review of patient test results, and staff interview, it was revealed the laboratory failed to follow its own policy to ensure the verification of CBC (complete blood count) results with flags. The findings were: 1. A review of the manufacturer's instructions for the Beckman Coulter AcT Diff 2 hematology analyzer (PN 4237495A) under table "6.4 What Flags Mean" revealed the manufacturer identified the following flags as possible flags on CBC results: 1 2 3 4 M 2. A review of the laboratory's policy titled "Protocol for Flags" revealed: "3. If flags persist in the report a new sample will be collected from the patient for retesting." "5. Results with an "*" flag (may represent interference with WBC count), will be reanalyzed if sample is available, repeat the test with a new patient sample if flag persists." "6. The WBC differential will be crossed out and/not reported on the chart. A clinical decision will be made to submit specimen to a reference laboratory for testing." 3. A random sampling of 10 patient charts from patients tested from December 2016 to April 17, 2018 (the date of the survey) revealed the following 5 patients whose CBC results had flags which were reported to the healthcare provider, however the laboratory did not have documentation of verifying the results: Date Patient ID Flag(s) 04-25-2017 000042116 2 01-17-2017 000042116 2, M 01-13-2017 000101307 3 12-27-2016 000101307 M 11-02-2017 10 /25/2008 * 03-12-2018 000101512 3 03-09-2018 000101512 * 02-19-2018 000101717 * 4. The laboratory was asked to provide documentation of following its own policy to resolve CBC results with flags prior to their release to the healthcare provider. No documentation was provided. 5. An interview with testing personnel

	number 1 as listed on Form CMS-209 on 04/17/2018 at 1145 hours in the break room confirmed the findings. Key: WBC - white blood count CMS - Centers for Medicare and Medicaid Services
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review the laboratory's temperature logs, and confirmed in interview of facility personnel, the laboratory failed to perform corrective action for dates when the temperature in the laboratory was documented out of range. The findings were: 1. Review of the laboratory's "Temperature Log" revealed the laboratory had a defined room temperature range of 65-77 degrees Fahrenheit. 2. Random review of temperature records from January 2017 to December 2017 revealed the following dates when the temperature for the room was out of range: April 21, 2017 78 degrees Fahrenheit May 16, 2017 80 degrees Fahrenheit August 29, 2018 78 degrees Fahrenheit October 25, 2018 79 degrees Fahrenheit 3. The laboratory was asked to provide documentation of performing corrective action when the temperature was documented out of range. No documentation was provided. 4. An interview with testing personnel one as listed on Form CMS-2019 on 04/17/2018 in the break room confirmed the findings.
D6054	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 annually, after the first year. 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 files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 3 of 4 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS-209 (signed by the laboratory director on 04/12/2018) revealed the laboratory identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed that the technical consultant failed to perform annual competency assessments for 3 of 4 testing personnel who required them. Testing personnel 1: Employment date: 8-2007 to present (04-17-2018) Missing annual competency assessments for 2016 and 2017 Testing personnel 3: Employment date: 2005 to present (04-17-2018) Missing annual competency assessments for 2016 and 2017 Testing personnel 4: Employment date: 01-23-2015 to 08-2017 Missing annual competency assessments for 2016 3. The laboratory was asked to provide documentation of the missing competency assessments. No documentation was provided. 4. An interview with testing personnel number 1 as listed on Form CMS-209 on 04/17/2018 at 1045 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Serivces