

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0951615	<b>(X3) Date Survey Completed</b>  04/20/2021
<b>Name of Provider or Supplier</b>  Redbird Medical Center	<b>Street Address, City, State</b>  4323 South Hampton Road, Dallas, 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>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were 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.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on hematology control manufacturer's instructions, Beckman Coulter AcTDIFF 2 quality control (QC) records (1/2021 through 2/2021) and confirmed in staff interview, the laboratory failed to ensure the hematology control materials had not exceeded their expiration dates prior to testing for 15 of 43 days (1/2021 through 2/2021). Findings included: 1. Review of Clinical Diagnostic Solutions (CDS) 3PD Hematology Control package inserts (Rev: 06.05.16) provided the following information: CDS 3PD Hematology Control Opened: 01/08/2021 Kit Lot: 32008-1K</p>

EXP: 18-Jan-21 Levels: Low, Medium and High 2. Review of Beckman Coulter AcTDIFF 2 quality control (QC) records revealed the following days when three levels of expired CDS 3PD Hematology Control materials were utilized by the laboratory: Control Runs Lot # 32008 Exp Date: 01-18-2021 1/20/2021; 1/21/2021; 1/22/2021; 1/23/2021;1/24/2021;1/25/2021; 1/26/2021; 1/27/2021; 1/28/2021; 1/29/2021; 1/30/2021; 1/31/2021; 2/01/2021; 02/02/2021; 02/04/2021 The laboratory failed to ensure CDS 3PD Hematology Control materials had not exceeded their expiration dates prior to testing for 15 of 43 days (1/2021 through 2/2021). 3. In an interview with staff on 4/20/2021 at 11:30 AM in the breakroom, after review of QC records, the technical consultant 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 laboratory policy, hematology control material manufacturer's instructions, Beckman Coulter AcTDIFF 2 quality control (QC) records (01/2021 through 02/2021), patient records, and in staff interview, the laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of Beckman Coulter Act Diff 2 test performance with current and accurate statistical parameters for 15 of 43 days (01/2021 through 02/2021). Findings included: 1. Review of laboratory policy titled, "Tab 5: Analytic Policies and Procedures" stated the following: AcTDIFF 2 Analyzer "Control/Calibrator Storage and Stability...Sealed control and calibrator vials are stable until the expiration date marked on the package ....Quality Control Policies- Control procedures will detect immediate errors, performance over time, and variance in operator performance .... Verifying New Lot Numbers of Controls- At least one day before the current lot of control expires, verify the acceptability of the new lot number." 2. Review of the manufacturer package inserts for Clinical Diagnostic Solutions (CDS) 3PD Hematology Control package (Rev: 06.05.16) stated the following: Kit Lot: 32008-1K EXP: 18-Jan-21 In use date: 01/08/2021 Levels: Low, Medium and High 3. Review of the laboratory's quality control records for the Beckman Coulter AcTDIFF 2 revealed the following days when expired quality control materials were used prior to patient testing: Control Runs a. 1/20/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) b. 1/21/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) c. 1/22/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) d. 1/23/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) e. 1/24/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) f. 1/25/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) g. 1/26/2021 Lot # 32008 Exp Date: 01-

18-2021 All three levels performed (Low, Medium, and High) h. 1/27/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) i. 1/28/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) j. 1/29/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) k. 1/30/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) l. 1/31/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) m. 2/01/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) n. 2/02/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) o. 2/03/2021 Lot # 32008 Exp Date: 01-18-2021 All three levels performed (Low, Medium, and High) The laboratory failed to ensure quality control material used was within the specified expiration date and failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of Coulter Act Diff 2 test performance with current and accurate statistical parameters for 15 of 43 days (01/2021 through 2/2021). 4. Review of laboratory patient records revealed the following patients tested on the Beckman Coulter AcTDIFF 2 on days when expired quality control materials were used prior to patient testing: Date Performed and Patient Number. Refer to patient alias list. a. 01/21/2021 Patient ID: 102290 b. 01/22/2021 Patient ID: 040298; 100456 c. 01/23/2021 Patient ID: 042992; 122770 d. 01/24/2021 Patient ID- 051478; 032449; 100853; 120360; 040259; 020757; 081902 e. 01/25/2021 Patient ID: 102511 f. 01/26/2021 Patient ID: 082367; 031467 g. 01/27/2021 Patient ID: 083145; 112978; 113069; 122264; 053180; 010373; 041280 h. 01/28/2021 Patient ID: 121739; 021767 i. 01/29/2021 Patient ID: 100368; 120398 j. 01/30/2021 Patient ID: 100968; 122659; 122060; 052676 k. 01/31/2021 Patient ID: 042969; 091679; 052475; 051875 l. 02/01/2021 Patient ID: 101877; 050354 m. 02/02/2021 Patient ID: 111295 n. 02/03/2021 Patient ID: 100399 5. In an interview on 4/20/2021 at 11:30 AM, after review of QC records, the laboratory representatives confirmed the above findings.

**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's submitted Centers for Medicare and Medicaid (CMS -209) form, review of Proficiency testing records (2019-2021), review of the laboratory's personnel records, and in interview with staff, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 2 of 10 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS 209 form (signed by the laboratory director on 04/16/2021) revealed 8 Testing Persons (TP #1 - TP#8) performing moderate complexity testing on the Beckman Coulter AcTDIFF 2 hematology instrument. 2. Review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records from 2019 through 2021 revealed 2 testing persons, not listed on the CMS-209 form, performed proficiency testing in 2019 and 2020. Testing Person #9 and Testing Person #10 were added by the laboratory representatives to the submitted CMS-209 form. Further review of the AAFP proficiency testing records revealed Testing Person #9 performed testing on AAFP 2019-A, samples 04 and 05 and Testing Person #10 performed testing on AAFP 2020-B, samples 06 and 07. 3. A

review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency assessments at least twice the first year of patient testing for the following 2 of 10 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the Beckman Coulter AcTDIFF 2 hematology analyzer: a. Testing person #9; Date of Hire 06/29/2015 No documentation of personnel competency assessments at least twice the first year of patient testing for the Beckman Coulter AcTDIFF 2 hematology analyzer. b. Testing person #10; Date of Hire 05/19/2019 No documentation of personnel competency assessments at least twice the first year of patient testing for the Beckman Coulter AcTDIFF 2 hematology analyzer. 4. During an interview on 04/202021 at 11:00 am in the breakroom, the laboratory representatives were asked to provide documentation of personnel competency assessments at least twice the first year of patient testing for the Beckman Coulter AcTDIFF 2 hematology analyzer for TP#9 and TP#10. No documentation was provided. This confirmed the above findings.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of Proficiency testing records (2019-2021), review of the laboratory's personnel records, and in interview with staff, it was revealed the laboratory failed to have documentation of training for the following 2 of 10 testing persons to qualify them to perform moderate complexity testing: Findings included: 1. Review of the CMS 209 form (signed by the laboratory director on 04/16/2021) revealed 8 Testing Persons (TP #1 - TP#8) performing moderate complexity testing on the Beckman Coulter AcTDIFF 2 hematology instrument. 2. Review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records from 2019 through 2021 revealed 2 testing persons not listed on the CMS-209 form performed proficiency testing in 2019 and 2020. Testing Person #9 and Testing Person #10 were added by the laboratory representatives to the submitted CMS-209 form. Further review of the AAFP proficiency testing records revealed Testing Person #9 performed testing on AAFP 2019-A, samples 04 and 05. Testing Person #10 performed testing on AAFP 2020-B, samples 06 and 07. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for the following 2 of 10 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the Beckman Coulter AcTDIFF 2 hematology analyzer: a. Testing person #9; Date of Hire: 06/29/2015 No training documentation for the Beckman Coulter AcTDIFF 2 hematology analyzer b. Testing person #10; Date of Hire 05/11/2019 No training documentation for the Beckman Coulter AcTDIFF 2 hematology analyzer 4. During an interview on 04/202021 at 11:00 am in the breakroom, the laboratory representatives were asked to provide documentation of training for TP#9 and TP#10. No documentation was provided. The laboratory representative stated that TP#9 and TP#10 were initially hired as receptionists at other clinic locations. The laboratory representative was asked to provide a specific date when TP#9 and TP# 10 began moderate complexity testing. No date was provided. This confirmed the above findings.