

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0958089	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Randy D Roberts, Md	Street Address, City, State 1000 East Matthews, Jonesboro, AR	
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	. This is the CLIA recertification survey of the Laboratory conducted on 08/08/2018. At the time of recertification survey the laboratory was not in compliance with the following conditions: 42 CFR 493.803(a)(b)(c): Successful Participation 42 CFR 493.807: Reinstatement of Nonwaived Laboratories 42 CFR 493.1403: Moderate Complexity- Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: . Based on a review of the 2016 and 2017 CMS Casper Reports 153D, 155D and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory had unsuccessful performance in proficiency testing for the tests of White</p>

Blood Cell Differential (WBC DIFF), Granulocytes (GRANS), Lymphocytes (LYMPHS) and Monocytes (MONO) as evidenced by: Failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2130.

D2017

REINSTATEMENT OF NONWAIVED LABORATORIES

CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:

. Based on review of 2017 and 2016 CMS Casper Reports 155D, 153D, and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory had a subsequent unsuccessful performance for the test White Blood Cell Differential, Lymphocytes, Granulocytes, and Monocytes as cited at 2130.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

. A. Based on review of the 2017 and 2016 CMS Casper Reports 155D and 153D, and the American Proficiency Institute proficiency testing results, it was determined the laboratory failed two out of three proficiency testing for the tests of White Blood Cell Differential (WBC DIFF), Granulocytes (GRANS), Lymphocytes (LYMPHS) and Monocytes (MONO) as evidenced by: 1. The laboratory received a score of 0% for the test of WBC DIFF in the third proficiency event of 2016 and in the first proficiency event of 2017. 2. The laboratory received a score of 0% for the test of LYMPHS in the third proficiency testing event of 2016 and in the first proficiency event of 2017. 3. The laboratory received a score of 0% for the test of MONOs in the third proficiency testing event of 2016 and in the first proficiency event of 2017. 4. The laboratory received a score of 0% for the test of GRANS in the third proficiency testing event of 2016 and in the first proficiency event of 2017. B. Based on the review of the 2017 and 2016 CMS Casper Reports, it was determined the laboratory had three out of four consecutive failures which constitutes unsuccessful performance for the test White Blood Cell Differential (WBC DIFF), Granulocytes (GRANS), Lymphocytes (LYMPHS) and Monocytes (MONO) as evidenced by: 1. The

laboratory received a score of 0% for the test of WBC DIFF, 0% for the test of GRANS, 0% for the test of LYMPHS and 0% for the test of MONO in the third proficiency testing event of 2016. 2. The laboratory received a score of 0% for the test of WBC DIFF, 0% for the test of GRANS, 0% for the test of LYMPHS and 0% for the test of MONO in the first proficiency testing event of 2017. 3. The laboratory received a score of 0% for the test of WBC DIFF, 0% for the test of GRANS, 0% for the test of LYMPHS and 0% for the test of MONO in the third proficiency testing event of 2017.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
. Through a review of Quality Assessment Plan for Proficiency's testing, Proficiency Testing (PT) records for 2016, 2017 and 2018, Plan of Correction from 2017, as well as interviews with staff, it was determined that the Laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. As evidenced by: A review of the Laboratory's Quality Assessment Plan for Proficiency Testing (PT) revealed: "Since repeated PT failures can result in cease testing, PT reports should be reviewed promptly upon receipt. This review should identify the causes of any failures for the same test, instrument or range, similar to investigations for out of range QC. A yearly QA review of the entire PT process should assure: 1) PT samples are handled like patient specimens: 2) PT results are reviewed by staff: 3) Corrective action is taken and documented for all PT failures and 4) Correction action is effective in preventing future failures. B. A review of PT records for 2017 and 2016 revealed the laboratory failed White Blood Cell Differential in the third PT event of 2016, first PT event of 2017, and the third PT event of 2017. C. A Proficiency desk review survey was conducted by the State Agency on September 26, 2017 for the first unsuccessful Proficiency Test failure in White Blood Cell Differential. It was noted on the Plan of Correction received on October 11, 2017: " The Laboratory Director is responsible for ensuring all testing personnel successfully participates in proficiency testing showing competence in using the analyzer. Laboratory Director is responsible for ensuring a corrective action plan is being followed when unacceptable proficiency testing occurs." D. The Laboratory's Quality Assessment Plan did not prevent recurrence of problems in the first and third proficiency testing event of 2017, or the third proficiency testing event of 2016. E. In an interview on 8/8/2018 at 1300, the technical consultant (as listed on form CMS 209) confirmed the laboratory failed to prevent the recurrence of problems in the General Laboratory System.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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

	<p>This CONDITION is not met as evidenced by:</p> <p>. Through a review of proficiency testing results, laboratory correction action records, policy and procedure manual, it was determined the laboratory director failed to ensure that corrective action was effective and failed to provide overall management and direction as cited at: D6019: Laboratory director failed to ensure that corrective action was effective in proficiency testing. D6021: Laboratory director failed to ensure quality assessment programs are maintained.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on review of 2017 and 2016 proficiency testing scores, it was determined the laboratory director failed to ensure the correction action followed and was effective for the unsatisfactory performance for the test of White Blood Cell Differential as cited at D2130.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Through a review of the quality assessment policy, proficiency testing results, lack of documentation, as well as interviews with staff, it was determined the laboratory director failed to ensure that the quality assessment policies are maintained to assure quality laboratory services as cited at D 5291.</p>