

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2099494	(X3) Date Survey Completed 11/08/2018
Name of Provider or Supplier Allison H Henderson Md Pa	Street Address, City, State 1112 N Floyd Road, Suite 8, Richardson, TX	
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
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 review of AAB (American Association of Bioanalysts) proficiency testing results and interview with the Office Manager the laboratory failed to score at least 80% for Leucocytes for 2 (1st and 2nd testing event out of 2018) out of 4 testing events (1st, 2nd, 3rd testing event in 2018 and 3rd testing event in 2017) reviewed (See D2130).</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

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:

Based on review of AAB (American Association of Bioanalysts) proficiency testing results and interview with the Office Manager the laboratory failed to score at least 80% for Leucocytes for 2 (1st and 2nd testing event out of 2018) out of 4 testing events (1st, 2nd, 3rd testing event in 2018 and 3rd testing event in 2017) reviewed. Findings Included: Review of AAB proficiency testing results revealed a 0% for Leukocytes in the 1st and 2nd testing event in 2018. During an interview on 11/08/18 at 2:00 PM the Office Manager confirmed the failures.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Office Manager the laboratory failed to perform competency evaluations on 3 out of 3 Testing Personnel. Findings Included: Review of the CMS 209 the laboratory has 3 Testing Personnel. Review of the Testing Personnel files revealed no competency evaluations. During an interview on 11/08/18 at 1:30 PM the Office Manager confirmed that there had been no competency evaluations performed on the 3 Testing Personnel.

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Office Manager the laboratory failed to document the humidity of the room where testing was performed since 08/11/17. Findings Included: Review of the manufacturers instructions for the Complete Blood Count (CBC) analyzer revealed that the humidity should be between 30%-85%. Review of daily logs revealed that the humidity of the room where testing was performed was not documented. During an interview on 11/08/18 at 3:00 PM the Office Manager confirmed that the laboratory did not document the room humidity.

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 record review and interview with the Office manager the laboratory failed to follow their policy to document Quality Assurance (QA) monthly for 1 out of 1 year (2017-2018) reviewed. Findings Included: Review of policies dated 08/11/17 by the Laboratory Director, the laboratory was to document QA monthly. No documentation of monthly QA was provided. During an interview on 11/08/18 at 2:00 PM the Office Manager confirmed that there was no monthly QA documented.

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 AAB (American Association of Bioanalysts) proficiency testing results and interview with the Office Manager the Laboratory Director failed to ensure the laboratory scored at least 80% for Leucocytes for 2 (1st and 2nd testing event out of 2018) out of 4 testing events (1st, 2nd, 3rd testing event in 2018 and 3rd testing event in 2017) reviewed (See D6016).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of AAB (American Association of Bioanalysts) proficiency testing results and interview with the Office Manager the Laboratory Director failed to ensure the laboratory scored at least 80% for Leucocytes for 2 (1st and 2nd testing event out of 2018) out of 4 testing events (1st, 2nd, 3rd testing event in 2018 and 3rd testing event in 2017) reviewed. Findings Included: Review of AAB proficiency testing results revealed a 0% for Leukocytes in the 1st and 2nd testing event in 2018. During an interview on 11/08/18 at 2:00 PM the Office Manager confirmed the failures.