

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0874926	<b>(X3) Date Survey Completed</b>  04/03/2018
<b>Name of Provider or Supplier</b>  D Singh Md & Associates	<b>Street Address, City, State</b>  900 Mt Royal Blvd, Suite 2, Pittsburgh, PA	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation and tour of the laboratory and interview with Testing Personnel #1 (TP#1), the laboratory failed to document maintenance and calibration for 1 of 1 Eppendorf Repeater 1-5 ml Adjustable Pipette from 2017 to the time of survey. Findings include: 1. On the date of survey, 04/03/2018, TP #1 could not provide Eppendorf Repeater 1-5 ml Adjustable Pipette maintenance records. 2. The Eppendorf Repeater 1-5 ml Adjustable Pipette is used for mixing calibrators for the ACE Alera chemistry analyzer. 3. 420 chemistry specimen were in run in 2017. 4. TP#1 confirmed the findings above on 04/03/2018 around 10:30 am.</p>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless</p>

the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on review of calibration verification records and interview with Testing Personnel #1 (TP #1), the laboratory failed to perform calibration verification at least every six months for the Beckman Coulter Access 2 and the Alfa Wassenman Ace Alere Chemistry Analyzers from 2016 to the date of survey. Findings include: 1. On the date of survey, 04/03/2018, TP#1 provided calibration verification records for the Beckman Coulter Access 2 and the Alfa Wassenman Ace Alere analyzers that were performed in 2007. 2. TP#1 could not provided calibration verification records for the years of 2016 and 2017. 3. TP #1 confirmed the finding above on 04/03/2018 around 10:15 am.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on the review of Medical Laboratory Evaluation Program (MLE) 2016 and 2017 proficiency testing (PT) records and interview with laboratory personnel #1 (TP #1), the laboratory director failed to identify corrective actions (CA) for all proficiency testing reports 80% and below. Findings Include: 1. On the date of survey, 04/03/2018, review of MLE PT records revealed, that the laboratory did not document a CA for 4 of 5 PT score that were 80% or below. - MLE 2016 Chemistry Event 3 for ALP score of 80% - MLE 2016 Chemistry Event 3 for Iron, Total score of 80% - MLE 2016 Hematology Event 3 for Cell ID score of 80% - MLE 2017 Chemistry Event 1 for Cell ID score of 73% 2. TP #1 confirmed the findings above on 04/03 /2018 around 10:00 am.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on, the review of quality assessment records and interview with Laboratory Personnel #1 (TP#1), the Laboratory Director failed to ensure that quality assessment programs are maintained and documented to assure the quality of laboratory services provided from 06/16/2016 to the date of survey. Findings: 1. On the day of survey 04/03/2018, review of the laboratories quality assessment documents, revealed that the laboratory's quality assessment of the pre-analytic, analytic and post analytic phases have not been documented since 2016. 2. TP#1 confirmed the findings above. on 04/03/2018 around 11:20.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor record review and interview with the Testing personnel #1 (TP#1) , the technical consultant (Laboratory Director) failed to evaluate the competency of all testing personnel as required in 2017. Findings Include: 1. At the day of survey, 04/03/2018, review of competency records revealed that TP #1 competency was not assessed in 2017. 2. In 2017, 525 patient specimen were tested. 3. TP#1 confirmed the findings above on 04/03/2018 around 09:45 am.