

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2053679	(X3) Date Survey Completed 01/31/2019
Name of Provider or Supplier Sovah Family Medicine - Mt Hermon	Street Address, City, State 2767 Franklin Turnpike, Danville, VA	
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	An announced CLIA Recertification survey was conducted at the SOVAH Family Medicine Mt Hermon on January 31, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), quality control (QC) data and interview with the office manager, the laboratory failed to follow the established P&P for performing verification of each new lot number of QC material prior to use for three (3) of 3 lot numbers received in the calendar year 2018. Findings include: 1. Review of the P&P for "Quality Controls" revealed the following statement: "III. Procedure- 3. Each new lot number of quality controls is validated before placing the lot number in service." 2. Review of the Boule hematology QC records for the CDS Medonic M-series hematology instrument revealed the following lot numbers</p>

received in 2018: 21802-31, 21802-32, 21802-33 expiration date 06/26/2018- in use 03/26/2018, 21806-31, 21806-32, 21806-33, expiration date 09/24/2018- in use 06/25/2018, 21808-31, 21808-32, 21808-33, expiration date 12/24/2018- in use 09/24/2018. The inspector requested to review documentation of the verification of the new lot numbers of QC prior to use. The documentation was not available for review. 3. An interview with the office manager at approximately 12: 30 PM confirmed the above-specified findings.

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 the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, the quality assurance (QA) policy and an interview, the technical consultant failed to perform and document annual competency assessments for three (3) of 3 TP in 2017. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant that there were 3 TP performing patient testing in 2017. (See attached personnel list.) 2. Review of the TP records revealed no documentation of competency assessments performed by the technical consultant in 2017 for TP A, B and C. The inspector requested the competency assessments for the 3 TP. The documentation was not available for review. 3. Review of the QA policy revealed the following statement: "5. Personnel Assessment- III. Procedure- 3. All testing personnel will be evaluated for competency on an annual basis." 4. An interview with the office manager at approximately 12:30 PM confirmed that the above-specified findings.