

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0233214	(X3) Date Survey Completed 03/12/2020
Name of Provider or Supplier Memorial Family Care, Inc	Street Address, City, State 501 Rison Street Suite 120, 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 Memorial Family Care, Inc on March 12, 2020 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:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the operator's manual, instrument calibration and maintenance records, and an interview with the primary testing personnel (TP), the laboratory failed to follow manufacturer's instruction for performing calibration procedures following preventative maintenance procedures in 2018 and 2019. Findings include: 1. Review of the operator's manual for the Abbott Cell Dyn 1800 revealed the following statement: "Section 6- Calibration Procedures", "When to Calibrate-calibration is indicated following service adjustments (e.g. major component changes). Calibration is necessary when indicated by the results of quality control procedures. Calibration is also required following component replacement, software upgrade, and preventative maintenance or reagent changes." 2. Review of the</p>

calibration and maintenance records for the Cell Dyn 1800 instrument revealed that preventative maintenance was performed on 8/16/18 and 8/21/19. The inspector requested to review calibration procedures performed on or after the specified dates. The documentation was not available for review. 3. On 3/12/20 at approximately 12:00 PM, the primary TP stated that they were unaware that the manufacturer required the calibration procedures after preventative maintenance and that there was no calibration documentation available for review for the above-specified dates.

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, lack of documentation, and interview with the primary TP, the technical consultant (TC) failed to perform the annual competency assessment for one (1) of 3 TP in 2018. Findings include: 1. Review of the CMS-209 form revealed that there were a total of 3 TP performing patient testing in 2018. See attached TP code sheet. 2. Review of the TP records revealed lack of documentation by the TC of performance of the annual competency assessment for TP C in 2018. 3. An interview with the primary TP on 3/12/20 at approximately 12:00 PM confirmed the findings.