

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2019287	(X3) Date Survey Completed 01/03/2019
Name of Provider or Supplier Intermountain Tooele Instacare	Street Address, City, State 777 N Main Street, Tooele, UT	
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
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 lack of documentation, laboratory calibration records review, and interview with the laboratory technical consultant, the laboratory failed to perform calibration by the PocHi 100 manufacturer's instructions and their quality assessment procedure, at least once every six months for 1 of 4 six month periods reviewed between January 2017 and January 2019 (due May 2017). The laboratory performed approximately 1 complete blood count test each day of the week. Findings include: 1. The laboratory failed to document they followed Sysmex Pochi 100 instrument manufacturer's instructions to calibrate the instrument at least once every six months for the calibration due in May of 2017. 2. Calibration records review failed to include a calibration was performed between November 2016 and November 2017. 3. In an interview with the laboratory technical consultant on 01/03/2019 at approximately 12:15 P.M. the consultant stated the laboratory failed to document calibration performance for the first six month period of 2017.</p>