

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2056881	(X3) Date Survey Completed 02/01/2019
Name of Provider or Supplier Clarus Dermatology	Street Address, City, State 900 Long Lake Road Suite #150, New Brighton, MN	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a solution used for microscopic examinations was not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory performed microscopic examinations for fungus as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/01/19 at 10:10 a.m. 2. Expired stain solution bottles were observed as present and available for use during the tour. See below. Stain Lot Exp date Chlorazol Fungal Stain K138J1 Aug 2014 Chlorazol Fungal Stain K17221 2018-02-28 3. The microscopic examination testing logs indicated 28 patient samples were examined in 2017 and 28 patient samples were examined in 2018. As of date of survey, 4 patient samples had been examined in 2019. 4. In an interview on 02/01/19 at 10:20 a.m., TP1 confirmed expired solutions had been used to examine patient samples.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples at least annually. Findings are as follows: 1. The laboratory performed Serum hCG* testing using the Quick Vue hCG Combo test kit as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/01/19 at 10:10 a.m. 2. A requirement to assess testing personnel competency using proficiency testing samples was established in the Laboratory Testing Personnel Competency Assessment procedure located in the Laboratory Manual. Assessment using previously analyzed specimens, blind samples, or proficiency testing samples was not included in the Competency Documentation Form. 3. Laboratory records indicated 4 of 7 testing personnel (TP) were not assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples in 2017. In 2018, 5 of 7 TP were not assessed in this manner. See below. TP performed proficiency testing as indicated by "x" TP 2017 2018 1 x 2 x 3 4 x 5 N/A N/A 6 x 7 8 x N/A - not applicable, initial training performed in October 2018 4. In an interview on 02/01/19 at 11:05 a.m., TP1 confirmed the above finding. *Note hCG - Human Chorionic Gonadotropin (Pregnancy test)