

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0677186	(X3) Date Survey Completed 03/19/2018
Name of Provider or Supplier Middlebury Family Health	Street Address, City, State 1330 Exchange St, Ste 201, Middlebury, VT	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory testing personnel failed to attest to the routine integration of mycology and bacteriology proficiency testing (PT) samples using the laboratory's routine methods in 2016 and 2017. Findings include: 1) Review on 3/19/18 of Medical Laboratory Evaluation PT records revealed laboratory testing personnel did not sign the attestation statement form for two of two attestation forms reviewed from PT events in 2016, and three of three attestation forms reviewed from PT events in 2017. These five events included testing for potassium hydroxide (KOH) slide preparation procedures and throat cultures for the presumptive identification of beta-hemolytic Group A Streptococcus. 2) Interview on 3/19/18 at 11:25 a.m. with a licensed practical nurse who has administrative roles for the laboratory, confirmed testing personnel did not sign the five attestation forms reviewed for PT events in 2016 and 2017.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test mycology</p>

proficiency testing (PT) samples the same number of times it routinely tests patient samples in 2016 and 2017. Findings include: 1) Review on 3/19/18 of Medical Laboratory Evaluation (MLE) PT records from 2017 revealed three testing personnel performed potassium hydroxide (KOH) slide preparation testing, each, on two of two samples in event 2017 MLE-M2 prior to the date results were due to be submitted to the PT company for evaluation; and two testing personnel performed KOH slide preparation testing, each, on two of two PT samples in event 2017 MLE-M3 prior to the date results were due to be submitted to the PT company for evaluation. 2) Review on 3/19/18 of the laboratory's "KOH Preparation" procedure, effective 3/23/10, revealed no instruction for group analysis or repeat testing of KOH slide preparations for patient specimens. 3) Interview on 3/19/18 at 11:25 a.m. with a licensed practical nurse who has administrative roles for the laboratory, confirmed that the four PT samples for KOH preparation testing in events 2017 MLE-M2 and 2017 MLE-M3 were each performed by multiple testing personnel. It was further revealed that KOH preparation PT samples were often read by multiple testing personnel to reach a consensus before submitting results and that this practice was not part of the testing methods practiced for routine patient specimens.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to verify the accuracy of the saline wet mount procedure in 2016 and 2017. Findings include: 1) Review on 3/19/18 of proficiency testing (PT) records from 2016 and 2017 revealed the laboratory was not enrolled in PT for their saline wet mount procedure. 2) Interview on 3/19/18 at 11:25 a.m. with a licensed practical nurse who has administrative roles for the laboratory confirmed the above finding and revealed the laboratory did not perform any procedures to verify the accuracy of saline wet mounts in 2016 and 2017 through PT or other alternate methods. 3) The laboratory reported 39 saline wet mount tests in 2016, and 37 saline wet mount tests in 2017.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

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.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, procedures for evaluation of competency in 2016 and 2017 failed to include assessment of test performance for mycology and bacteriology testing. Findings include: 1) Review on 3/19/18 of proficiency testing (PT) records from 2016 revealed 2 of 6 testing personnel participated in potassium hydroxide (KOH) preparation testing, and 2 of 6 testing personnel participated in throat culture testing for the presumptive identification of beta-hemolytic Group A Streptococci. Review of PT records from 2017 revealed, 3 of 6 testing personnel participated in KOH preparation testing, and 3 of 6 testing personnel participated in

throat culture testing for the presumptive identification of beta-hemolytic Group A Streptococci. 2) Interview on 3/19/18 at 11:25 a.m. with a licensed practical nurse who has administrative roles for the laboratory confirmed the above finding. The LPN revealed the laboratory did not use an alternate method to assess test performance for those testing personnel who did not test KOH preparation and throat culture proficiency samples in 2016 and 2017.