

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0087070	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Garrison Women's Health	Street Address, City, State 770 Central Avenue, Dover, NH	
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 testing personnel and the laboratory director failed to attest to performing hematology, mycology, and parasitology proficiency testing (PT) in the same manner as routine patient samples in two of three events in 2017. Findings include: 1) Review on 8/21/2018 of microscopy procedure PT records from 2017 (three events) for fern test, semen analysis, potassium hydroxide slide preparation (KOH prep), and saline wet mount slide examination (wet mount) revealed the laboratory director failed to sign the attestation form for the first event in 2017 and the one testing personnel who performed the microscopy procedures failed to sign the attestation form for the second event. 2) Interview on 8/21/2018 at 10:15 a.m. with the laboratory manager/testing personnel confirmed above finding.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of mycology and parasitology testing at least twice in 2017. Findings</p>

include: 1) Review on 8/21/2018 of proficiency testing (PT) records from 2017 for wet mount preparation (wet mount) testing revealed the laboratory failed to obtain an acceptable score for one (of one) PT samples tested in the first event and for one (of one) PT sample in the third event. 2) Interview on 8/21/2018 at 10:15 a.m. with the laboratory manager/testing personnel confirmed the above finding. The laboratory manager revealed the laboratory did not perform any other testing to verify the accuracy of wet mount testing in 2017.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to evaluate the unacceptable proficiency testing (PT) result for wet mount preparation in the first PT event of 2017. Findings include: 1) Review on 8/21/2018 of PT records from 2017 (three events) revealed the laboratory failed to obtain an acceptable result for wet mount testing for one (of one) PT sample in the first event of 2017. Review of the "Performance Review and Corrective Action Documentation" (evaluation report) form revealed the laboratory director signed the form but failed to document what action was taken to address the unacceptable result. 2) Interview on 8/21/2018 at 10:15 a.m. with the laboratory manager/testing personnel confirmed there was no documentation of follow up action taken on the evaluation report.

D5425

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(3)

The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to determine control procedures based on performance specifications established in 2017 by the laboratory for bacteriology testing. Findings include: 1) Review on 8/21/2018 of the control procedures for group B Streptococcus (GBS), and Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) testing revealed instruction to perform control testing for each new lot number of corresponding reagents. 2) Review on 8/21/2018 of the laboratory's control records for GBS and CT/NG confirmed control material was tested for each new lot number. Further review revealed 7 of 8 GBS lot numbers lasted longer than 20 days and 7 of 14 reagent lot numbers for CT/NG lasted longer than 20 days. 3) Review on 8/21/2018 of the data obtained by the laboratory in August 2017 as part of the laboratory's risk assessment for individualized quality control plan revealed the laboratory ran acceptable controls for twenty consecutive days using the same lot number of GBS, CT/NG but didn't account for the length of time a lot number may be in use before changing to the next lot number. 4) Interview on 8/21/2018 at 12:10 p.m. with the laboratory manager/testing personnel confirmed the above findings. 5) The laboratory has performed and reported 123 patient GBS and CT/NG tests.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to establish policies and procedures for monitoring testing personnel to assure that testing personnel performing mycology, parasitology, hematology, and bacteriology are competent to perform test procedures and to identify needs for remedial training or continuing education to improve skills. Findings include: 1) Review on 8/21/2018 of competency assessments revealed no documentation of competency assessments for 12 of 12 testing personnel who performed fern test, semen analysis, potassium hydroxide slide preparation (KOH prep), and wet mount slide preparation (wet mount). 2) The laboratory could not provide at the time of survey a policy or procedure for competency assessments for all testing personnel including those who performed fern test, semen analysis, potassium hydroxide slide preparation (KOH prep), and wet mount slide preparation (wet mount). 3) Interview on 8/21/2018 at 10:45 a.m. with the laboratory manager/testing personnel confirmed the laboratory did not have a policy and procedure in place for performing competency assessments and that the worksheet used for competency assessments of some testing personnel was not used for the assessment of competency of the 12 testing personnel performing fern tests, semen analysis, KOH preps, and wet mounts.

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 record review and staff interview, the technical consultant failed to evaluate the competency of testing personnel performing hematology, mycology, and parasitology in 2017. Findings include: 1) Review on 8/21/2018 of proficiency testing (PT) records for fern testing, semen analysis, potassium hydroxide slide preparation (KOH prep), and wet mount slide preparation (wet mount) from 2017 revealed 9 of 12 testing personnel who performed these tests did not participate in a PT event. Of the three testing personnel who did participate, one testing personnel failed to demonstrate competency in test performance for wet mount and one failed to demonstrate competency in wet mount and KOH prep. The laboratory could not provide documentation that evaluations of competency were done which included all

requirements for an evaluation of competency found at 493.1413(b)(8). 2) Interview on 8/21/2018 at 10:45 a.m. with the laboratory manager/testing personnel confirmed the above finding. The laboratory manager revealed the laboratory did not use other methods to evaluation test performance other than PT and the testing personnel performing the tests listed above were not evaluated for competency for all elements outlined at 493.1413(b)(8).

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and staff interivew, the technical consultant failed to evaluate new testing personnel performing mycology, parasitology and hematology testing twice in the first year of testing patient specimens spanning 2017 and 2018. Findings include: 1) Review on 8/21/2018 revealed two new testing personnel; Staff A was hired 2/13/2017 and Staff B was hired 8/15/2017. 2) Review on 8/21/2018 of proficiency testing (PT) records from 2017 and 2018 for fern test, semen analysis, wet mount preparation (wet mount), and potassium hydroxide preparation (KOH prep) revealed Staff A did not participate in PT in 2017 or 2018 and Staff B participated in the first PT event for 2018 but failed to obtain an acceptable results for wet mount testing. 3) Interview on 8/21/2018 at 10:45 a.m. with the laboratory manager/testing personnel confirmed competency assessments were not performed on Staff A and Staff B at least twice in the first year the individuals were hired and began testing and revealed Staff B did not receive another evaluation of test performance for wet mount testing following the failed PT.