

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0955701	<b>(X3) Date Survey Completed</b>  12/22/2020
<b>Name of Provider or Supplier</b>  Winchester Womens Healthcare	<b>Street Address, City, State</b>  27 Main St, Andover, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA paper desk review of proficiency testing was conducted for the Winchester Womens' Healthcare, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the Bacteriology subspecialty, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing review for calendar year 2020 (two testing events) of American Proficiency Testing (API) proficiency testing results, the laboratory failed</p>

to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the Bacteriology subspecialty as evidenced by the following: Refer to D2020 and D2028. .

**D2020**

**BACTERIOLOGY**  
CFR(s): 493.823(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:  
Based on record review of calendar year 2020 American Proficiency Institute (API) proficiency testing results, the laboratory failed to attain a testing event score of at least 80 percent for all Bacteriology analytes resulting in unsatisfactory performance as evidenced by the following testing event scores: Bacteriology (throat cultures): 1. 2020 API testing event 2 - score of 0 % (failure to participate - refer to D2025). 2. 2020 API testing event 3 - score of 0 % (failure to participate - refer to D2025). The results were confirmed with API on 12/16/20 and via a telephone interview with the laboratory director on 12/18/20 at 2:09 PM. .

**D2025**

**BACTERIOLOGY**  
CFR(s): 493.823(c)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:  
Based on a review of proficiency testing results and confirmed through interview with the laboratory director on 12/18/20, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program resulting in a score of 0% for the testing event. Findings revealed the following: Bacteriology: 1. 2020 API testing event 2 - score of 0 % (failure to participate). 2. 2020 API testing event 3 - score of 0 % (failure to participate). The failure to participate was confirmed with API on 12/16/20 and via a telephone interview with the laboratory director on 12/18/20 at 2:09 PM. .

**D2028**

**BACTERIOLOGY**  
CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on proficiency testing review of American Proficiency Institute (API) proficiency testing results for calendar year 2020 (two testing events), the laboratory failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events for the subspecialty of Bacteriology resulting in unsuccessful performance as evidenced by the following testing event scores:

Bacteriology: 1. 2020 API testing event 2 - score of 0 % (failure to participate - refer to D2025). 2. 2020 API testing event 3 - score of 0 % (failure to participate - refer to D2025). The results were confirmed with API on 12/16/20 and via a telephone interview with the laboratory director on 12/18/20 at 2:09 PM.