

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2074395	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Quick Care Urgent	Street Address, City, State 202 Governors Drive, Huntsville, AL	
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
D2016	<p>SUCCESSFUL PARTICIPATION 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 a review of CMS Casper reports (#153/#155), a review of API (American Proficiency Institute) proficiency testing performance evaluations, and a telephone interview with the Laboratory Manager (also a testing personnel), the surveyor determined the laboratory failed to successfully participate in proficiency testing for two consecutive testing events, Event #1 and #2 of 2018. The laboratory failed to participate in Event #2, 2018, resulting in a zero percent score. These failures resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. A review of the Casper reports revealed the laboratory failed to successfully perform in RBC (Red Blood Cell Count, Hematology testing) for Events #1 and #2 of 2018. The</p>

	<p>laboratory scored 60 % for the RBC for Event #1, 2018 and 0 % for Event #2. 2. The API performance evaluations revealed the laboratory scored zero percent for Event #2, 2018, due to the laboratory's failure to participate in the testing event. The surveyor confirmed the 60 % RBC score for Event #1, 2018 with the API evaluations. 3. In a telephone interview at 1:20 PM on 9/20/18, the Laboratory Manager stated the failure to participate occurred because the new laboratory staff did not know to run the proficiency testing samples. The laboratory had an increased turn-over of testing personnel. The laboratory staff analyzed the samples after the API result submission date. The Laboratory Manager had recently become testing personnel and could not respond to the failure for Event #1, 2018.</p>
<p>D2127</p>	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing performance evaluations, and an interview with the Laboratory Manager, the surveyor determined the laboratory scored zero percent for the Red Blood Cell Count (RBC) for Event #2, 2018 (Failure to Participate), due to the laboratory's failure to return the results to API within the established time-frame for grading. This is unsatisfactory proficiency testing performance by the laboratory. The findings include: 1. A review of the API performance evaluations revealed the laboratory scored zero percent (0 %) for Event #2, 2018, due to the laboratory's failure to participate. 2. In a telephone interview on 9/20/18 at 1:20 PM, the Laboratory Manager stated the laboratory had new staff, who did not realize the proficiency testing samples needed to be analyzed. The samples were tested after the deadline of result submission, resulting in a zero percent score (Failure to Participate) by API.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of CMS Casper reports (#153/#155), a review of API (American Proficiency Institute) proficiency testing performance evaluations, and a telephone interview with the Laboratory Manager (also a testing personnel), the surveyor determined the laboratory failed to perform satisfactorily in proficiency testing for Red Blood Cell Count, Hematology testing (RBC) for two consecutive testing events, Event #1 and #2 of 2018. The laboratory failed to participate in Event #2, 2018, resulting in a zero percent score. These failures resulted an an initial unsuccessful proficiency testing participation for the laboratory. The findings include: 1. Refer to D2016.</p>
<p>D6017</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p>

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of CMS Casper reports (#153/#155), a review of API (American Proficiency Institute) proficiency testing performance evaluations, and a telephone interview with the Laboratory Manager (also a testing personnel), the surveyor determined the Laboratory Director failed to ensure proficiency testing samples were tested, and the results returned to API within the established timeframe for grading for Event #2, 2018, Hematology testing. The failure to submit the results within the established time-frame resulted in zero percent scores (Failure to Participate). The findings include: 1. A review of the Casper report #155 for Event #2, 2018 revealed the laboratory scored zero percent (0 %) for Hematology testing. 2. A review of the API performance evaluations revealed the laboratory scored 0 % for Event #2, 2018, due to the laboratory's failure to participate. 3. In a telephone interview on 9/20/18 at 1:20 PM, the Laboratory Manager stated the laboratory had new staff, who did not realize the proficiency testing samples needed to be analyzed. The samples were tested after the deadline of result submission, resulting in a zero percent score (Failure to Participate) by API. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor