

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D0084686	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Hematology & Oncology Assoc Of Rhode Island	Street Address, City, State 1220 Pontiac Ave Ste 101, Cranston, RI	
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
D0000	A proficiency testing desk review was conducted pursuant to 42 CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 record review and staff interview the laboratory failed to successfully perform in two consecutive proficiency (PT) testing events for the regulated analytes cell identification and white blood cell (WBC) differential for (PT) program for Event 3 2017 and Event 1 2018 in the specialty of hematology. Refer to D2130 and D2122</p>
D2122	HEMATOLOGY

CFR(s): 493.851(b)

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 and staff interview the laboratory failed to ensure satisfactory performance in two out of three consecutive proficiency testing (PT) events for the cell identification and white blood cell (WBC) differential in the speciality of hematology. Findings include: 1. Record review of PT records provided by the American Proficiency Institute (API) on 8/22/18 revealed the following results: 2017, Event 3 - score of 0% in the specialty of hematology for Cell I.D / WBC Differential. 2018, Event 1 - score of 20% in the specialty of hematology for Cell I.D / WBC Differential. 2. Interview with the laboratory technologist (LT) on 8/21/18 at 10:30 a. m. confirmed these findings. The LT further revealed that the LT believes the methodology/machine error caused the incorrect results of testing.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to ensure satisfactory performance in two out of three consecutive proficiency testing (PT) events for the cell identification and white blood cell (WBC) differential in the speciality of hematology. Findings include: 1. Record review of PT records provided by the American Proficiency Institute (API) on 8/22/18 revealed the following results: 2017, Event 3 - score of 0% in the specialty of hematology for Cell I.D / WBC Differential. 2018, Event 1 - score of 20% in the specialty of hematology for Cell I.D / WBC Differential. 2. Interview with the laboratory technologist (LT) on 8/21/18 at 10:30 a. m. confirmed these findings. The LT further revealed that the LT believes the methodology/machine error caused the incorrect results of testing.