

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2040640	(X3) Date Survey Completed 08/18/2023
Name of Provider or Supplier Zoomcare Laboratory	Street Address, City, State 11956 Sw Garden Pl, Tigard, OR	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of the Wisconsin State Health Laboratory (WSHL) proficiency testing (PT) and Casper Report 0155D, the laboratory had unsuccessful participation for the 1st and 2nd event of 2023 for the specialty Hematology. Refer to D2128 and D2130.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons

other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on review of the Wisconsin State Health Laboratory (WSHL) proficiency testing (PT) and Casper Report 0155D, the laboratory had unsuccessful participation for the 1st and 2nd event of 2023 for the analyte WBC differential/Cell differential. Findings include: 1. WSHL 1st Event 2023 WBC differential/Cell differential = 8%. 2. WSHL 2nd Event 2023 WBC differential/Cell differential = 8%.

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 review of the Wisconsin State Health Laboratory (WSHL) proficiency testing (PT) and Casper Report 0155D, the laboratory had unsuccessful participation for the 1st and 2nd event of 2023 for the analyte WBC differential/Cell differential. Findings include: 1. WSHL 1st Event 2023 WBC differential/Cell differential = 8%. 2. WSHL 2nd Event 2023 WBC differential/Cell differential = 8%.