Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2138758	04/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Exer Medical Corporation	25548 The Old Road, Ste U1, Santa Clarita, CA	

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	D2016 Based on Surveyor review of laboratory's proficiency testing (PT) results from API, and interview with the laboratory technical consultant on April 14, 2024, at 12: 45 p.m., the laboratory failed to successfully participate in the proficiency testing program for the hematocrit test. The findings include: 1. The laboratory participated in the API PT testing program for hematocrit in the specialty of hematology in the year 2025. However, it received an unsatisfactory score of 40% at the 1st and 3rd events for the hematocrit test which resulted in unsuccessful PT participation (see D2130). Therefore, the accuracy of the patients' hematocrit test results rendered by the laboratory in 2025 cannot be assured. 2. The laboratory technical consultant on April 14, 2026, at 12:45 p.m., affirmed that the laboratory did not receive a satisfactory score for the hematocrit test at the 1st and 3rd events in 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/6/2026, stated that the laboratory performed approximately 720 hematocrit tests, annually. Lab: "All the outliers noted above are clinically insignificant outliers, indicating random error - on repeat analysis: Hem-04 HCT 41.7, Hem-05 34.0 & Hem-05 RBC 4.14, all of which are within acceptalbe peer range... D6000 The laboratory director failed to ensure the maintenance of an acceptable levels of analytical performance for the hematocrit test. (See D6023)
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:
D2130	HEMATOLOGY CFR(s): 493.851(f) (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 Surveyor review of laboratory's proficiency testing (PT) results from API, and interview with the laboratory technical consultant on April 14, 2026, at 12:45 p. m., the laboratory failed to achieve satisfactory performance for the hematocrit test in two out of three consecutive events which resulted in an unsuccessful performance for the test. The findings include: 1. The laboratory participated in the API PT testing program for hematocrit test in the specialty of hematology in 2025. However, it received an unsatisfactory score of 40% at the 1st and 3rd events for the hematocrit test that resulted in an unsatisfactory analyte performance. Laboratory's failure to achieve satisfactory performance for the same analyte in two out of three consecutive events resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical consultant on April 14, 2026, at 12:45 p.m., affirmed that the laboratory received an unsatisfactory score of 40% at the1st and 3rd events in 2025 for the hematocrit test. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/6/2026, stated that the laboratory performs approximately 720 hematocrit tests, annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute (API) records for 2025-1 and 2025-3 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and API records for 2025-1 and 2025-3 events, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2130 .
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from API, and interview with the laboratory technical consultant on April 14, 2026, at 12:45 p. m., the laboratory failed to achieve satisfactory performance for hematocrit test in two out of three consecutive PT events. The findings include: See D2130.