Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0710715	07/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Spectracell Laboratories Inc	6030 North Course Dr, Houston, TX	

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 PTDR (Proficiency testing desk review) was performed on 07/14/2026. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
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 a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual

	Laboratory Profile and verified with College of American Pathologists (CAP), the laboratory failed to attain successful performance for 2 of 2 consecutive testing events in the specialty of Hematology for the regulated analyte of WBC Differential for 2 of 2 proficiency testing events (2026 1st event and 2026 2nd event), resulting in an initial PT failure. Refer to D2130 and D2131. Key: WBC=White blood cell PT=Proficiency testing
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 a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the proficiency testing company CAP, the laboratory failed to achieve successful performance for 2 of 2 consecutive testing events in the specialty of Hematology for the regulated analyte of WBC Differential for 2 of 2 proficiency testing events (2026 1st event and 2026 2nd event), resulting in an initial PT failure. The findings were: 1. Review of the CASPER Report 155 Individual Laboratory Profile revealed the laboratory received unsatisfactory scores in 2026 1st event and 2026 2nd event. WBC Differential 2026 1st event: 0% 2026 2nd event: 0% 2. Review of the CAP Proficiency Testing records confirmed the laboratory received the above results for the WBC Differential in 2 of 2 proficiency testing events in 2026. Key: CAP=College of American Pathologists
D2131	HEMATOLOGY CFR(s): 493.851(g) (g) 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 a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 153 Unsatisfactory (failed) and Unsuccessful (2 of 3) PT Report and Report 155 Individual Laboratory Profile, the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the specialty of Hematology for 2 of 2 proficiency testing events in 2026, resulting in unsuccessful performance. The findings were: 1. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 153 Unsatisfactory (failed) and Unsuccessful (2 of 3) PT Report revealed the laboratory failed to achieve an overall satisfactory performance (80% or greater) for consecutive testing events for 2 of 2 proficiency testing events in 2026. 2026 Hematology Event: 1 Score: 50 Event: 2 Score: 50 2. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile revealed the laboratory failed to achieve an overall satisfactory performance (80% or greater) for consecutive testing events in the

	specialty of Hematology for 2 of 2 proficiency testing events in 2026. 2026 Hematology 2026 Event 1 Score: 50% 2026 Event 2 Score: 50% Key: CAP=College of American Pathologists PT=Proficiency Testing
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 desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the proficiency testing company College of American Pathologists (CAP) for 2026 1st event and 2026 2nd event, 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 desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with College of American Pathologists (CAP), the laboratory failed to attain successful performance for 2 of 2 consecutive testing events in specialty of Hematology for a regulated analyte of WBC Differential for 2 of 2 proficiency testing events (2026 1st event and 2026 2nd event), resulting in an initial PT failure. Refer to D2130 and D2131. Key: WBC=White blood cell PT=Proficiency testing