

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2144349	(X3) Date Survey Completed 05/04/2022
Name of Provider or Supplier Bernhardt Laboratories Inc	Street Address, City, State 950 River Edge Court, Longwood, FL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of gynecologic cytology proficiency testing (PT) enrollment records, review of gynecologic cytology PT participation records and interviews with the Laboratory Director/Technical Supervisor, Facility A (CLIA #10D2144349) failed to enroll in an annual CMS-approved gynecologic cytology PT program for annual testing in 2020, 2021 and to the date of the survey May 03, 2022. Facility A additionally failed to notify CMS of the receipt of gynecologic cytology PT sets from Facility B (CLIA #10D0645099) in 2020, 2021 and 2022 (refer to D2013). Findings include: 1. The Survey Team requested and Facility A failed to provide annual gynecologic cytology PT enrollment records for 2020, 2021 and to the date of the survey May 03, 2022. 2. During an interview on May 3, 2022 at 9:45 AM, the Laboratory Director/Technical Supervisor confirmed the laboratory performed gynecologic cytology testing in 2020, 2021 and 2022 and did not enroll in an annual CMS-approved gynecologic cytology PT program in 2020, 2021 and to the date of the survey May 03, 2022. 3. Facility A received annual gynecologic cytology PT sets of 10 slides from Facility B in 2020, 2021 and 2022 and failed to notify CMS of the receipt of the gynecologic cytology PT sets from Facility B (refer to D2013). a. The Laboratory Director/Technical Supervisor tested on the 10-slide testing set #34423 on</p>

October 6, 2020. b. The Laboratory Director/Technical Supervisor tested on the 10-slide testing set #34459 on February 9, 2021. c. The Laboratory Director/Technical Supervisor tested on the 10-slide testing set #34364 on February 9, 2022.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on interviews with the Laboratory Director/Technical Supervisor and review of gynecologic cytology PT records Facility A received a gynecologic cytology PT set consisting of 10 slides from Facility B in 2020, 2021 and 2022. Facility A failed to notify CMS of the receipt of the PT sets from Facility B for testing in 2020, 2021 and 2022. Findings include: 1. During an interview on May 3, 2022 at 9:45 AM, the Laboratory Director/Technical Supervisor stated the following: a. The 10-slide gynecologic cytology PT sets were received at Facility A from Facility B, via FedEx or courier in 2020, 2021 and 2022. b. There was no approved cytology proctor on-site at Facility A to administer the annual gynecologic cytology PT set to the Laboratory Director/Technical Supervisor in 2020, 2021 and 2022. c. The Laboratory Director /Technical Supervisor took the 10-slide gynecologic cytology PT examination at Facility A and then returned the 10-slide gynecologic cytology PT set and documents to Facility B via FedEx or courier in 2020, 2021 and 2022. 2. The Survey Team reviewed annual gynecologic cytology PT records from 2020, 2021 and 2022 for the Laboratory Director/Technical Supervisor. While the gynecologic cytology PT records stated the CLIA number for the PT event was for Facility B, the Laboratory Director/Technical Supervisor performed the PT testing event at Facility A. a. The Laboratory Director/Technical Supervisor tested on the 10-slide testing set #34423 on October 6, 2020. b. The Laboratory Director/Technical Supervisor tested on the 10-slide testing set #34459 on February 9, 2021. c. The Laboratory Director/Technical Supervisor tested on the 10-slide testing set #34364 on February 9, 2022. 3. During an interview on May 3, 2022 at 1:40 PM: a. The Laboratory Director/Technical Supervisor stated that Facility A was not aware they could not receive 10-slide gynecologic cytology PT sets from Facility B because that is the same way patient specimen slides were evaluated between the two facilities. b. The Laboratory Director /Technical Supervisor confirmed Facility A received the 10-slide gynecologic cytology PT sets referred from Facility B for testing. Slide testing sets include: -10-slide testing set #34423 on October 6, 2020 -10-slide testing set #34459 on February

	<p>9, 2021 -10-slide testing set #34364 on February 9, 2022 c. The Laboratory Director /Technical Supervisor confirmed Facility A failed to notify CMS that gynecologic cytology PT sets were received from Facility B for testing in 2020, 2021 and 2022.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of cytology PT enrollment records, lack of laboratory PT policies and procedures and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2020, 2021 and to the date of the survey May 03, 2022 (refer to D6088).</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records, lack of laboratory PT policies and procedures and interviews with the Laboratory Director/Technical Supervisor the Laboratory Director failed to ensure that Facility A enrolled in a CMS-approved annual gynecologic cytology PT program for 2020, 2021 and to the date of the survey May 03, 2022. Findings include: 1. The Laboratory Director failed to provide records of annual enrollment in a CMS-approved gynecologic cytology PT program in 2020, 2021 and to the date of the survey May 03, 2022. a. During an interview on May 3, 2022 at 9:45 AM, the Laboratory Director/Technical Supervisor stated, "I did not enroll this laboratory" and confirmed that the laboratory did not have any record of enrollment in an annual CMS-approved gynecologic cytology PT program in 2020, 2021 and to the date of the survey May 04, 2022. 2. The Laboratory Director failed to ensure written policies and procedures were established to detail Facility A enrollment in a CMS-approved annual gynecologic cytology PT program. 3. During an interview on May 3, 2022 at 1:40 PM, when asked if the laboratory had a policy for enrolling and participating in a CMS-approved annual gynecologic cytology PT program, the Laboratory Director/Technical Supervisor replied "no".</p>
<p>D9999</p>	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>