

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2007671	(X3) Date Survey Completed 05/14/2026
Name of Provider or Supplier Bhs Dermatology Center	Street Address, City, State Benbrook Medical Center, Butler, PA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Practice Manager (PM), the laboratory failed to monitor and document room humidity (RH) to ensure operating conditions were met for 1 of 1 Olympus BX45TF microscope and 2 of 2 Leica cryostats used to perform histopathology microscopic slide examinations from 06/26/2024 to 05/14/2026. Findings include: 1. On the day of the survey, 05/14/2026 at 09:45 am, the laboratory failed to provide documentation for the monitoring of RH to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 06/26/24 to 05/14/2026: - 1 of 1 Olympus BX45TF microscope (manufacturer's operating environment specifications: 5-40 degrees Celsius, maximum 80 % relative humidity) - 1 of 1 Leica 1520 Cryostat (manufacturer's operating environment specifications: 18-35 degrees Celsius maximum 60 % relative humidity) - 1 of 1 Leica 1860 Cryostat (manufacturer's operating environment specifications: 18-35 degrees Celsius maximum 60 % relative humidity) 2. The laboratory performed 1,586 histopathology microscopic slide examinations in 2025 (CMS 116, estimated annual volume, dated 04/15/2026). 3. The PM confirmed the above findings on 05/14/2026 at 10:40 am.</p>

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Cryostat Maintenance logs, lack of documentation, and interview with the Practice Manager (PM), the laboratory failed to document the corrective action taken when operating temperatures for the Cryostat were outside of the laboratory's established acceptable range for 27 of 79 days when histopathology testing was performed from 03/01/2025 to 11/30/2025. Findings include: 1. On the day of survey, 05/14/2026 at 09:50 am, review of the laboratory's Cryostat Maintenance logs revealed the following operating temperatures for the Cryostat were not within the laboratory's established acceptable range (below -20 to -30 degrees Celsius) when microscopic histopathology examinations were performed for 27 of 79 days from 03/01/2025 to 11/30/2025: - 03/20/2025: (-31C) - 05/05/2025: (-31C) - 06/11/2025: (-31C) - 09/10/2025: (-31C) - 09/11/2025: (-31C) - 09/15/2025: (-31C) - 09/16/2025: (-31C) - 09/18/2025: (-31C) - 09/23/2025: (-31C) - 09/24/2025: (-31C) - 09/25/2025: (-31C) - 09/30/2025: (-31C) - 10/07/2025: (-31C) - 10/08/2025: (-31C) - 10/09/2025: (-31C) - 10/14/2025: (-31C) - 10/16/2025: (-31C) - 10/20/2025: (-31C) - 10/21/2025: (-32C) - 10/23/2025: (-32C) - 10/28/2025: (-32C) - 10/29/2025: (-32C) - 10/30/2025: (-32C) - 11/03/2025: (-32C) - 11/04/2025: (-32C) - 11/05/2025: (-31C) - 11/10/2025: (-32C) 2. The laboratory could not provide documentation of corrective actions taken when the Cryostat operating temperatures were not within the laboratory's established acceptable range. 3. The laboratory performed 1,586 histopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 04/15/2026). 4. The PM confirmed the above findings on 05/14/2026 at 10:40 am.