

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0943813	<b>(X3) Date Survey Completed</b>  10/23/2024
<b>Name of Provider or Supplier</b>  John Q Binhlam, Md Pc	<b>Street Address, City, State</b>  1649 Westgate Circle, Suite 100, Brentwood, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the posted cryostat maintenance policy, the cryostat temperature log, and staff interview, the laboratory failed to perform corrective action for temperatures outside the stated temperature range for 47 of 47 days in 2023 and 2024. The findings include: 1. Observation of the laboratory on 10/23/2024 at 11:35 a.m. revealed an Avantik QS11 Cryostat (Serial Number 56215) in use for processing tissue for Mohs micrographic surgical specimens. 2. A review of the posted cryostat maintenance policy revealed the following requirement: "1. Console temperature is recorded daily. The cryostats should be maintained at -21 *C to no colder than -26*C for best sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." 3. A review of the cryostat temperature log revealed the following dates when the recorded temperatures were outside the laboratory's acceptable range with no corrective action performed: 08/30/23, 09/06/23, 09/13/23, 10/18/23, 10/25/23, 11/01/23, 11/15/23, 11/29/23, 12/13/23, 12/20/23, 12/27/23, 01/03/24, 01/10/24, 01/31/24, 02/07/24, 02/14/24, 02/21/24, 02/28/24, 03/13/24, 03/20/24, 03/27/24, 04/03/24, 04/17/24, 04/24/24, 05/01/24, 05/08/24, 05/22/24, 05/29/24, 06/05/24, 06/12/24, 06/19/24, 06/26/24, 07/03/24, 07/10/24, 07/17/24, 07/24/24, 07/31/24, 08/07/24, 08/14/24, 08/28/24, 09/04/24, 09/11/24, 09/18/24, 09/25/24, 10/02/24, 10/09/24, 10/23/24. 4. An interview with the office manager on 10/23/2024 at 3:00 p.m. confirmed the survey findings.</p>