

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2313231	(X3) Date Survey Completed 12/12/2025
Name of Provider or Supplier Fox Chase Cancer Ctr Doylestown	Street Address, City, State 610 Farm Lane, Doylestown, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the Laboratory Manager (LM), the laboratory failed to monitor and document room temperature and relative humidity for 71 of 99 days to ensure substantial proof of efficacy was provided for reagents and operating conditions were met for reliable test system operation when chemistry testing was performed from 09/04/2025 to 12/12/2025 as required per PA regulations. Findings include: 1. The PA State regulation 5.46 stated: "Reagents, procedures or equipment which have been demonstrated to be inadequate for clinical laboratory use as evidenced by reliable data from generally acceptable scientific testing and evaluating sources shall be prohibited for use by clinical laboratories upon specific notification by the Department. Also, reagents, equipment and procedures which do not have substantial proof of efficacy either by trial or extended use experience shall be prohibited for routine use". 2. On the day of the initial survey, 12/12/2025 at 10:37 am, the laboratory could not provide documentation for monitoring room temperature and relative humidity for 71 of 99 days to ensure proper storage of reagents and operating conditions were met for the following reagents used in the laboratory from 09/04/2025 to 12/12/2025: - Siemens Healthcare Diagnostics Clinitest hCG pregnancy test kit (manufacturer's acceptable temperature range 2C to 30 C) - Nova Biomedical StatStrip glucose test strips (manufacturer's acceptable temperature range: 15C to 40C, manufacturer's acceptable humidity range: 10 to 90% RH) 3. The laboratory performed 200 chemistry tests in 2025. (CMS 116 estimated annual volume, dated 10 /21/2025). 4. The LM confirmed the above findings on 12/12/2025 at 10:54 am.</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to establish and follow procedures to assess the competency of 1 of 2 Technical Supervisors (TS) and 1 of 2 General Supervisors (GS) for their supervisory responsibilities performed from 09/04/2025 to 12/12/2025. Findings Include: 1. On the day of the initial survey, 12/12/2025 at 9:35 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 1 of 2 TS (TS #2, CMS 209, dated 12/22/2025) and 1 of 2 GS (GS #2, CMS 209, dated 12/22/2025) for their supervisory responsibilities performed in the laboratory from 09/04/2025 to 12/12/2025. 2. The laboratory could not provide competency assessment documentation for the supervisory responsibilities of TS #2 and GS #2 when overseeing Mohs microscopic slide examinations performed from 09/04/2025 to 12/12/2025. 3. Review of the laboratory's Mohs test logs revealed the laboratory performed 26 Mohs microscopic slide examinations from 09/04/2025 to 12/12/2025. 4. The LM confirmed the findings above on 12/12/2025 at 10:54 am.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Mohs Quality Assurance (QA) policy, lack of documentation, and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure an established QA program was maintained to ensure the quality of services provided by the laboratory for 3 of 3 months from 09/04/2025 to 12/12/2025. Findings include: 1. The laboratory's Mohs Quality Assurance policy stated, " The QA program is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). Completion of the quality assurance program will be documented in the quality assurance log." 2. On the date of the initial survey, 12/12/2025 at 10:47 am, the laboratory could not provide documentation of the quality assurance log used to assess the laboratory's pre-analytical, analytical, and post-analytical processes for 3 of 3 months from 09/04/2025 to 12/12/2025. 3. Review of the laboratory's Mohs test logs revealed the laboratory performed 26 Mohs microscopic slide examinations from 09/04/2025 to 12/12/2025. 4. The LM confirmed the findings above on 12/12/2025 at 10:54 am.