

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0925440	(X3) Date Survey Completed 04/30/2026
Name of Provider or Supplier Deaconess Clinic Inc/Downtown	Street Address, City, State 120 S E 4th Street, Evansville, IN	
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 complaint survey was completed 04/30/2026. The following condition-level deficiencies were found to be out of compliance: D5200 42 CFR 493.1230 Condition: General Laboratory Systems
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and staff interviews, the laboratory failed to ensure the following: Employee competency was assessed for one of five testing personnel who performed high complexity Histopathology slide reading in 2023, 2024, and 2025 (Refer to D5209). Twice annual verification of microscopic slide review accuracy was completed for one of five testing personnel who performed high complexity Histopathology slide reading in 2023, 2024, and 2025 (Refer to D5217). Quality Assessment reviews included one of five testing personnel in 2023, 2024, and 2025. (Refer to D5293)</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and interviews, the laboratory failed to assess employee competency for one of five testing personnel performing high complexity Histopathology testing for 2023, 2024 and 2025. Findings include: 1. In interview on 4/21/2026 at 1:15 pm, E1 (Practice Administrator) stated that E2 (Testing Personnel) performed Histopathology slide reading at their location. 2. E2 analyzed the following patients' Histopathology samples microscopically: Patient Resulted Clinical Diagnosis P1 08/09/2023 SCC P2 07/13/2023 Melanoma in situ P3 08/15/2024 SCC in situ P4 08/16/2024 BCC P5 09/24/2025 S. Keratosis v/s A.Macule P6 09/25/2025 A. Keratosis/SCC in situ P7 02/23/2026 BCC 3. Upon request for yearly competency for E2 on 4/21/26 at 2:55 pm, E1 confirmed that no competency assessment was completed for E2 for 2023, 2024, and 2025. 4. In interview on 4/21 /2026 at 2:55 pm, E1 confirmed testing performed by E2 was billed under this CLIA number. 5. Review of the Laboratory Personnel Report (CLIA), signed 4/23/2026 by owner representative E5, showed the laboratory listed five high-complexity testing personnel performing Histopathology testing, including E2. Legend: BCC-Basal Cell Carcinoma E-Employee P-Patient SCC- Squamous Cell Carcinoma S.Keratosis - Seborrhic Keratosis A. Keratosis-Actinic Keratosis A. Macule - Asymmetric Macule v/s- versus

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and interviews, the laboratory failed to verify the accuracy of the Histopathology microscopic slide review completed by one of five testing personnel twice annually for 2023, 2024, and 2025. Findings include: 1. In an interview on 4/21/2026 at 1:15 pm, E1 (Practice Administrator) stated E2 (Testing Personnel) performed Histopathology slide reading at their location. 2. E2 analyzed patient Histopathology samples microscopically from August 9,2023 to February 23, 2026. (Refer to D5209) 3. Upon request for twice annual verification of E2's microscopic slide reading on 04/21/2026 at 2:55 pm, E1 confirmed that the laboratory did not complete twice annual verification for E2's for 2023, 2024, and 2025.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and interviews, the laboratory failed

to include one of five testing personnel (E2) in Quality Assessment reviews for 2023, 2024, and 2025. Findings include: 1. In an interview on 4/21/2026 at 1:15 pm, E1 (Practice Administrator) stated E2 (Testing Personnel) performed Histopathology slide reading at their location. 2. E2 analyzed patient Histopathology samples microscopically from August 9, 2023 to February 23, 2026. (Refer to D5209) 3. Upon request for documentation that E2 was involved in the quality assessment program on 04/21/2026 at 4:00 pm, E1 confirmed that E2 had not participated in quarterly Quality System Assessment meetings since 12/01/2022. E2 continued to microscopically read tissue samples and complete final biopsy reports.