Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0925440	01/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Deaconess Clinic Inc/Downtown	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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain Mohs micrographic surgery (Mohs) quality control (QC) slides for two (PT#1 and PT#4) out of six patients reviewed. Findings included: 1. "Mohs Laboratory Procedure Manual", signed by laboratory director on 1/2/23, under section "Daily Quality Control for Hematoxylin and Eosin Stains" states "All slides are retained and kept on file at the facility." 2. Review of Mohs patient reports and slides revealed the following: a. PT#1 had no QC slide with 15 slides read on 4/1/2021. b. PT#4 had no QC slide with three slides read on 9/2/2021. 3. During interview on 1/31/2023 at 12:44 PM, SP-1 (Histotech) indicated the previous dermatologist would throw QC slides in the trash after review.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to verify the accuracy of Mohs testing for one (2022) of two years reviewed. Findings included: 1. Review of "Quality Assurance Review", signed by laboratory director on 8/24/22, revealed peer-review was performed January 2022 to June 2022 on 8/24/22 for 23 Mohs cases. There was no documentation that peer-review was completed for Mohs cases the second half of 2022. 2. Review of the "Mohs Laboratory Procedure Manual", signed by laboratory director on 1/2/23, indicated the laboratory had no policy on how twice annual verification will be performed. 3. During an interview on 1 /31/2023 at 2:49 PM, SP-1 (Histotech) confirmed peer-review was not performed for the second half of 2022 for Mohs testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to define and maintain temperatures for two (Leica CMS 1850 and Leica CMS 1860) of two cryostats in use for Mohs slides from October 2020 to January 2023. Findings include: 1. During tour of the laboratory on 1/31/23 at 11:18 AM, the following equipment was observed: Leica CMS 1850 Cryostat Machine and Leica CMS 1860 Cryostat Machine. 2. The manual "Leica CM1510S", version 08/2003, under 6.7 "Temperature selection chart required the following temperatures: a) Skin with fat -25 degrees Celsius (C) - -35 degrees C) Skin without fat -15 degrees C - 25 degrees C. 3. Review of policy "Cryostat Maintenance", signed by laboratory director on 1/2/23, read "If temperature is ever below -30 degree C or higher than -20 degree C corrective action is taken and documented." 4. Review of "Cryostat Temperature Log" from 2020 to 2023 indicated each cryostat had their own log "A" and "B": a) Logs for Cryostat A required the temperature to read between "-18 to -25 degrees C". b) Fiscal year 2020 -2021 logs for Cryostat A revealed temperatures warmer than -18 degrees C for 71 days out of 181 days and colder than -25 degrees C for 19 of 181 days from October 2020 to September 2021. c) Fiscal year 2021 to 2022 logs for Cryostat A revealed temperatures colder than -25 degrees C for 100 out of 174 days from October 2021 to September 2022. d) Fiscal year 2022 to 2023 logs for Cryostat A revealed temperatures colder than -25 degrees C for 64 out of 64 days from October 2022 to January 2023. e) Logs for Cryostat B required the temperature to read between "-18 to -25 degrees C". f) Fiscal year 2021 to 2022 logs for Cryostat B revealed temperatures colder than -25 degrees C for 165 out of 174 days from October 2021 to September 2022. g) Fiscal year 2022 to 2023 logs for Cryostat B revealed temperatures colder than -25 degrees C for 64 out of 64 days from October 2022 to January 2023. 5. In interview on 1/31/2023 at 2:49 pm, SP-1, acknowledged they did not know which cryostat temperature was correct in policy or on the logs from 2021 to 2023.