Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1010660	02/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Healthstar Physicians-Bartlette	1907 West Morris Blvd Suite G, Morristown, TN	

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	During a recertification survey performed on 02.26.2024, the laboratory was found out of compliance with the following condition: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
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 observation of the laboratory, review of quality assurance records, and interview with the laboratory director, the laboratory failed to verify the accuracy of Mohs histopathology testing at least twice annually in 2022 and 2023. The findings include: 1. Observation of the laboratory on 02.26.2024 at 9:30 a.m. revealed equipment and stains in use for preparing tissue removed during Mohs surgery for histopathology procedures. 2. Review of laboratory quality assurance proficiency testing records used for verification of accuracy for Mohs histopathology procedures revealed the lab failed to verify accuracy twice annually in 2022 and 2023. 3. Interview with the laboratory director on 02.26.2024 at approximately 12:15 p.m. confirmed the laboratory failed to verify the accuracy of its' Mohs histopathology procedures twice annually in 2022 and 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory and staff interview, the laboratory failed to ensure that reagents were used prior to their expiration date in 2022 and 2023. The findings include: 1. Observation of the Mohs histopathology laboratory on 02.26.2024 at 9:30 a.m. revealed the following expired marking dyes on the counter: -one bottle Avantik Yellow marking dye (lot 133861 expired on 10.31.2023) -one bottle Avantik Blue marking dye (lot 122849 expired on 05.31.2023) -one bottle Avantik Green marking dye (lot 118659 expired on 03.31.2023) -one bottle Avantik Red marking dye (lot 093059 expired on 01.31.2022) -one bottle Avantik Black marking dye (lot 094358 expired on 01.31.2022) -one bottle Avantik Orange marking dye (lot 9213 expired on 08.31.2021) 2. Interview with the lead testing person on 02.26.2024 at 9:30 a.m. confirmed the above survey findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Laboratory testing personnel performing high complexity inking of tissue removed during Mohs histopathology procedures failed to meet the regulatory education requirements (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, interview with testing personnel number two (TP2 listed on the Centers for Medicare and Medicaid Services Personnel Report, CMS-209), review of personnel records, and interview with the laboratory director, the testing personnel performing high-complexity testing failed to meet the regulatory education requirements. The findings include: 1. Observation of the laboratory on 02.26.2024 at 9:30 a.m. revealed reagents, stains, and inks in use for performing histopathology procedures for tissues obtained by the Mohs surgical procedure. 2. Interview with TP2 on 02.26.2024 at 9:45 a.m. revealed that tissue is brought to the lab by the Mohs surgeon and the histotech (TP2) performs inking of the tissue. 3. Review of testing personnel records revealed TP2 did not have the required education to perform high-complexity testing. 4. Interview with the laboratory director on 02.26.2024 at 11:30 a.m. confirmed the histotech (TP2) performing inking of tissues removed during the Mohs histopathology surgical procedure did not meet the required regulatory education requirements to perform high-complexity testing.