

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D1093164	<b>(X3) Date Survey Completed</b> 02/09/2021
<b>Name of Provider or Supplier</b> Hahn Medical Practices Inc	<b>Street Address, City, State</b> 215 South Louisiana Avenue, Martinsburg, WV	
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>D0000</b>	An announced, on site, recertification survey was conducted at Hahn Medical Practices Inc on February 9, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures (P&amp;P), a tour of the lab, and an interview with the office manager, the laboratory failed to document and retain all analytic systems activities regarding the processing and H&amp;E staining for patient MOHs testing. Findings: 1. Review of written P&amp;P identified a "Quality Assurance For Routine Stains" that stated " All reagents and supplies used in the lab will be documented upon opening and put in use. This will consist of open date, lot number, expiration date" . No documentation of this information for 2019 or 2020 could be located. 2. A tour of the laboratory identified the reagents currently in use at the laboratory to be within the expiration date and suitable for use. 3. During an interview with the office manager, on 2/9/2021 at approximately 9:50 AM, the office manager stated that completed laboratory reagent logs for 2019 and 2020 could not be located.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</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.

This STANDARD is not met as evidenced by:

Based on a review of laboratory written policies and procedures (P&P), personnel files, and an interview with the office manager, the laboratory failed to document the competency evaluation of the 1 laboratory personnel that performs the tissue slide preparation and H&E slide staining. Findings: 1. Review of written P&P identified a personnel policy that stated personnel evaluations performed yearly. 2. Review of the personnel file for 1 of 1 laboratory personnel identified a documented annual competency evaluation from 2/28/2019. No annual competency evaluation for 2020 could be located. 3. During an interview with the office manager, on 2/9/2021 at approximately 8:30 AM, the office manager stated that the 2020 annual competency evaluation for the 1 of 1 laboratory personnel could not be located.

**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 a review of laboratory written policies and procedures (P&P), MOHs patient testing logs, Quality Assurance (QA) records, and an interview with the office manager, the laboratory failed to document General Laboratory Systems QA activities for 13 of 14 months of patient testing. Findings: 1. Review of P&P identified "Quality Assurance for Routine Stains" that stated "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems." 2. Review of patient MOHs testing logs identified patient MOHs testing on 6/6/19, 6/20/19, 7/18/19, 8/1/19, 8/15/19, 9/4/19, 10/3/19, 10/14/19, 10/16/19, 10/28/19, 10/30/19, 12/9/19, 12/11/19, 12/30/19, 1/13/20, 1/27/20, 2/3/20, 2/17/20, 2/24/20, 3/2/20, 3/16/20, 3/23/20, 6/10/20, 6/17/20, 6/18/20, 6/24/20, 7/1/20, 7/2/20, 7/8/20, 7/22/20, 8/6/20, 8/13/20, 8/19/20, 8/27/20, 8/28/20, 12/30/20, 1/14/21, 1/28/21. 3. Review of QA records identified no documentation for the Monthly Quality Assurance Checklist for 13 of the 14 months of patient MOHs testing (6/19, 7/19, 8/19, 9/19, 10/19, 12/19, 1/20, 2/20, 3/20, 6/20, 7/20, 12/20, and 1/21.) 4. During an interview with the office manager, on 2/9/2021 at approximately 9:30 AM, the office manager stated that no documentation of the Monthly QA for the 13 of the 14 months could be located.

**D5393**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(b)(c)

The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on a review of laboratory written policies and procedures (P&P), MOHs patient testing logs, Quality Assurance (QA) records, and an interview with the office manager, the laboratory failed to document Preanalytic Systems QA activities for 13 of 14 months of patient testing. Findings: 1. Review of P&P identified "Quality Assurance for Routine Stains" that stated "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems." 2. Review of patient MOHs testing logs identified patient MOHs testing on 6/6/19, 6/20/19, 7/18/19, 8/1/19, 8/15/19, 9/4/19, 10/3/19, 10/14/19, 10/16/19, 10/28/19, 10/30/19, 12/9/19, 12/11/19, 12/30/19, 1/13/20, 1/27/20, 2/3/20, 2/17/20, 2/24/20, 3/2/20, 3/16/20, 3/23/20, 6/10/20, 6/17/20, 6/18/20, 6/24/20, 7/1/20, 7/2/20, 7/8/20, 7/22/20, 8/6/20, 8/13/20, 8/19/20, 8/27/20, 8/28/20, 12/30/20, 1/14/21, 1/28/21. 3. Review of QA records identified no documentation for the Monthly Quality Assurance Checklist for 13 of the 14 months of patient MOHs testing (6/19, 7/19, 8/19, 9/19, 10/19, 12/19, 1/20, 2/20, 3/20, 6/20, 7/20, 12/20, and 1/21.) 4. During an interview with the office manager, on 2/9/2021 at approximately 9:30 AM, the office manager stated that no documentation of the Monthly QA for the 13 of the 14 months could be located.

**D5609**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory patient MOHs testing logs, quality control (QC) logs, and an interview with the office manager, the laboratory failed to (f) document QC for the H&E staining process on each day of patient testing. Findings: 1. Review of patient MOHs testing logs identified patient MOHs testing on 6/6/19, 6/20/19, 7/18/19, 8/1/19, 8/15/19, 9/4/19, 10/3/19, 10/14/19, 10/16/19, 10/28/19, 10/30/19, 12/9/19, 12/11/19, 12/30/19, 1/13/20, 1/27/20, 2/3/20, 2/17/20, 2/24/20, 3/2/20, 3/16/20, 3/23/20, 6/10/20, 6/17/20, 6/18/20, 6/24/20, 7/1/20, 7/2/20, 7/8/20, 7/22/20, 8/6/20, 8/13/20, 8/19/20, 8/27/20, 8/28/20, 12/30/20, 1/14/21, 1/28/21. 2. Review of the QC log identified no QC documented for 7/2/20, 7/8/20, and 8/28/20. 3. During an interview with the office manager, on 2/9/21 at approximately 9:15 AM, the office manager stated that QC for H&E staining was not documented for 7/2/20, 7/8/20, and 8/28/20. The office manager stated that patient testing was documented in the MOHs testing log book for 7/2/20, 7/8/20, and 8/28/20.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of laboratory written policies and procedures (P&P), MOHs patient testing logs, Quality Assurance (QA) records, and an interview with the office manager, the laboratory failed to document Analytic Systems QA activities for 13 of 14 months of patient testing. Findings: 1. Review of P&P identified "Quality Assurance for Routine Stains" that stated "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems." 2. Review of patient MOHs testing logs identified patient MOHs testing on 6/6/19, 6/20/19, 7/18/19, 8/1/19, 8/15/19, 9/4/19, 10/3/19, 10/14/19, 10/16/19, 10/28/19, 10/30/19, 12/9/19, 12/11/19, 12/30/19, 1/13/20, 1/27/20, 2/3/20, 2/17/20, 2/24/20, 3/2/20, 3/16/20, 3/23/20, 6/10/20, 6/17/20, 6/18/20, 6/24/20, 7/1/20, 7/2/20, 7/8/20, 7/22/20, 8/6/20, 8/13/20, 8/19/20, 8/27/20, 8/28/20, 12/30/20, 1/14/21, 1/28/21. 3. Review of QA records identified no documentation for the Monthly Quality Assurance Checklist for 13 of the 14 months of patient MOHs testing (6/19, 7/19, 8/19, 9/19, 10/19, 12/19, 1/20, 2/20, 3/20, 6/20, 7/20, 12/20, and 1/21.) 4. During an interview with the office manager, on 2/9/2021 at approximately 9:30 AM, the office manager stated that no documentation of the Monthly QA for the 13 of the 14 months of patient testing could be located.

**D5893**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(b)(c)

(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of laboratory written policies and procedures (P&P), MOHs patient testing logs, Quality Assurance (QA) records, and an interview with the office manager, the laboratory failed to document Post Analytic Systems QA activities for 13 of 14 months of patient testing. Findings: 1. Review of P&P identified "Quality Assurance for Routine Stains" that stated "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems." 2. Review of patient MOHs testing logs identified patient MOHs testing on 6/6/19, 6/20/19, 7/18/19, 8/1/19, 8/15/19, 9/4/19, 10/3/19, 10/14/19, 10/16/19, 10/28/19, 10/30/19, 12/9/19, 12/11/19, 12/30/19, 1/13/20, 1/27/20, 2/3/20, 2/17/20, 2/24/20, 3/2/20, 3/16/20, 3/23/20, 6/10/20, 6/17/20, 6/18/20, 6/24/20, 7/1/20, 7/2/20, 7/8/20, 7/22/20, 8/6/20, 8/13/20, 8/19/20, 8/27/20, 8/28/20, 12/30/20, 1/14/21, 1/28/21. 3. Review of QA records identified no documentation for the Monthly Quality Assurance Checklist for 13 of the 14 months of patient testing (6/19, 7/19, 8/19, 9/19,

10/19, 12/19, 1/20, 2/20, 3/20, 6/20, 7/20, 12/20, and 1/21.) 4. During an interview with the office manager, on 2/9/2021 at approximately 9:30 AM, the office manager stated that no documentation of the Monthly QA for the 13 of the 14 months of patient testing could be located.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on a review of personnel files, Quality Control (QC) records, and laboratory records, the laboratory director (LD) failed to ensure that the laboratory personnel are performing the test methods as required. Findings: 1. A review of personnel files identified a laboratory personnel evaluation for 1 of 1 laboratory personnel for 2019. No documentation of an evaluation for 2020 could be located. See D5209. 2. A review of QC records identified 3 days of patient MOHs testing that had no daily QC documented. See D5609. 3. A review of laboratory records identified no documentation of lot numbers and expiration dates for reagent and supplies during 2019 and 2020. See D3031.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

The laboratory director must ensure that the 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 a review of the laboratory Quality Assessment (QA) documents, the laboratory director failed to ensure that the QA monitoring systems for the assurance of reliable and accurate test methods of the laboratory were performed and documented. Findings: 1. A review of QA records for the laboratory identified 13 of 14 months of patient testing had no QA monitoring documented. See D5293, D5393, D5793, and D5893.