

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0863880	(X3) Date Survey Completed 11/18/2024
Name of Provider or Supplier M H Al-Midani Md	Street Address, City, State 4050 Walli Strasse Dr, Burton, MI	
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
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow its competency assessment policies to assess testing personnel competency (refer to D5209), failed to verify the accuracy of its histopathology testing at least twice annually (refer to D5217), failed to perform and document control procedures for each date of patient testing for its routine and special stains (refer to D5473), and failed to perform and document positive and negative control reactivity for its immunohistochemical testing each time of use (refer to D5475).</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> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory director, the laboratory failed to follow its competency assessment policies to assess testing personnel competency for two (November 2022 to November 2024) of two years reviewed. Findings include: 1. A review of the laboratory's "2nd Opinion/Consultation Review" policy revealed a section stating, "Peer Review- On an ongoing basis, the pathologists</p>

are required to examine a representative sample of cases (benign, suspicious, atypical and malignant) signed out by different pathologists for QA/QC peer review. The actual number of cases involved in this process will be based on the overall specimen volume and will comply with the requirements outlined by the State Department of Health. The results of the exercise will be documented in this Policy and Procedure Manual." 2. A review of the laboratory's "Histopathology Diagnosis Accuracy Review" log revealed the most recent review was performed for testing personnel was 10/22/22. 3. An interview on 11/18/24 at 2:44 pm with the laboratory director confirmed competency assessments for testing personnel had not been performed in 2023 and 2024.

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 and interview with the laboratory director, the laboratory failed to verify the accuracy of its histopathology testing at least twice annually for two (November 2022 to November 2024) of two years reviewed. Findings include: 1. A review of the laboratory's "2nd Opinion/Consultation Review" policy revealed a section stating, "Peer Review- On an ongoing basis, the pathologists are required to examine a representative sample of cases (benign, suspicious, atypical and malignant) signed out by different pathologists for QA/QC peer review. The actual number of cases involved in this process will be based on the overall specimen volume and will comply with the requirements outlined by the State Department of Health. The results of the exercise will be documented in this Policy and Procedure Manual." 2. A review of the laboratory's "Histopathology Diagnosis Accuracy Review" log revealed the most recent review was performed for the laboratory was 10/22/22. 3. An interview on 11/18/24 at 2:44 pm with the laboratory director confirmed twice annual verification of accuracy testing for its histopathology testing had not been performed in 2023 and 2024.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the laboratory director, the laboratory failed to perform and document control procedures for each date of patient testing for its routine and special stains for 62 of 66 total patient testing dates between November 2022 and November 2024. Findings include: 1. A review of the laboratory's "Quality Control of Routine Hematoxylin Eosin Staining" policy revealed a section stating, "The Pathologist will review each slide for quality and either sign off on the 'Quality Control Sheet- Slide evaluation Checklist' provided by the lab or reject the slide set

and notify the lab or any irregularities or deficiencies." 2. A review of the laboratory's "Quality Control Stains IHC & Special Stains" policy revealed a section stating, "Special stains and IHC controls are run along with patient samples daily. H&E controls are run daily to test the quality of the staining reagents; a supervising pathologist will view these slides before patient samples are stained. All controls will be archived for retrieval. Immunohistochemical and Special Stains will all be interpreted with the use of positive control stains and a negative control tissue stain. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Positive control stains will be run for each patient group and will be labeled accordingly. A log will be kept that documents if the control slides are of acceptable quality." 3. An interview on 11/18/24 at 3:33 pm with the laboratory director revealed the laboratory had used the reference laboratory's log that was submitted to the laboratory with the list of cases and stains prepared. 4. A review of the laboratory's technical reference laboratory's list of cases processed prior to sending the specimen slides to the laboratory for reading titled "Sterling Pathology Daily Quality Control For Al-Midani" revealed a lack of documentation of stain quality for hematoxylin and eosin (H&E) staining and lack of positive and negative reactivity for its Alcian Blue, H. pylori, Periodic-Acid Schiff (PAS), and its Grocott-Gimri's methenamine silver (GMS) staining for the following batches of slides received: a. 11/22/2022, 12 cases with H&E, two cases with Alcian Blue, and four cases with H. pylori. b. 11/25/2022, 13 cases with H&E, one case with Alcian Blue, and one case with H. pylori. c. 12/15/2022, 17 cases with H&E, 10 cases with Alcian Blue, and nine cases with H. pylori. d. 12/29/2022, 30 cases with H&E, nine cases with Alcian Blue, and four cases with H. pylori. e. 01/19/2023, 43 cases with H&E, nine cases with Alcian Blue, and seven cases with H. pylori. f. 02/07/2023, 20 cases with H&E, five cases with Alcian Blue, and four cases with H. pylori. g. 02/21/2023, 41 cases with H&E, eight cases with Alcian Blue, and eight cases with H. pylori. h. 02/23/2023, two cases with H&E. i. 03/03/2023, 11 cases with H&E, three cases with Alcian Blue, and two cases with H. pylori. j. 03/17/2023, 10 cases with H&E, six cases with Alcian Blue, and four cases with H. pylori. k. 04/10/2023, 16 cases with H&E, five cases with Alcian Blue, and three cases with H. pylori. l. 04/25/2023, seven cases with H&E, two cases with Alcian Blue, and one case with H. pylori. m. 05/04/2023, 20 cases with H&E, seven cases with Alcian Blue, and six cases with H. pylori. n. 05/08/2023, nine cases with H&E, two cases with Alcian Blue, and two cases with H. pylori. o. 05/19/2023, 36 cases with H&E, 14 cases with Alcian Blue, and seven cases with H. pylori. p. 06/09/2023, 18 cases with H&E, six cases with Alcian Blue, and two cases with H. pylori. q. 06/15/2023, 29 cases with H&E, five cases with Alcian Blue, and three cases with H. pylori. r. 06/19/2023, two cases with H&E. s. 06/27/2023, seven cases with H&E, two cases with Alcian Blue, and two cases with H. pylori. t. 06/29/2023, 12 cases with H&E, five cases with Alcian Blue, and three cases with H. pylori. u. 06/30/2023, three cases with H&E. v. 07/14/2023, 12 cases with H&E, one case with Alcian Blue, and one case with H. pylori. w. 07/20/2023, 22 cases with H&E, eight cases with Alcian Blue, and five cases with H. pylori. x. 08/08/2023, eight cases with H&E, five cases with Alcian Blue, and four cases with H. pylori. y. 08/15/2023, 27 cases with H&E, 14 cases with Alcian Blue, and 10 cases with H. pylori. z. 08/29/2023, 11 cases with H&E, three cases with Alcian Blue, and two cases with H. pylori. aa. 09/06/2023, one case with H&E. bb. 09/11/2023, 28 cases with H&E, five cases with Alcian Blue, and four cases with H. pylori. cc. 09/25/2023, 19 cases with H&E, four cases with Alcian Blue, and four cases with H. pylori. dd. 09/26/2023, five cases with H&E, one case with Alcian Blue, and one case with H. pylori. ee. 09/27/2023, one case with H&E. ff. 10/04/2023, 14 cases with H&E, six cases with Alcian Blue, and five cases with H. pylori. gg. 10/11/2023, 28 cases with H&E and one case with Alcian Blue. hh. 11/14/2023, 31 cases

with H&E, 12 cases with Alcian Blue, and eight cases with H. pylori. ii. 11/21/2023, 22 cases with H&E. jj. 11/22/2023, 10 cases with H&E. kk. 11/24/2023, 13 cases with H&E, three cases with Alcian Blue, and one case with H. pylori. ll. 11/28/2023, 18 cases with H&E and one case with Alcian Blue. mm. 12/05/2023, 17 cases with H&E, six cases with Alcian Blue, and six cases with H. pylori. nn. 12/22/2023, 28 cases with H&E, six cases with Alcian Blue, and four cases with H. pylori. oo. 12/23/2023, 18 cases with H&E, seven cases with Alcian Blue, and five cases with H. pylori. pp. 01/12/2024, 11 cases with H&E, five cases with Alcian Blue, and four cases with H. pylori. qq. 01/23/2024, 16 cases with H&E, four cases with Alcian Blue, three cases with PAS, and three cases with H. pylori. rr. 02/07/2024, seven cases with H&E, three cases with Alcian Blue, and two cases with H. pylori. ss. 02/10/2024, three cases with H&E, two cases with Alcian Blue, one case with PAS, and one case with H. pylori. tt. 02/13/2024, six cases with H&E, one case with Alcian Blue, one case with PAS, and one case with H. pylori. uu. 02/23/2024, five cases with H&E, one case with Alcian Blue, one case with PAS, and one case with H. pylori. vv. 02/27/2024, four cases with H&E. ww. 03/01/2024, 17 cases with H&E, eight cases with Alcian Blue, four cases with PAS, and four cases with H. pylori. xx. 03/06/2024, 15 cases with H&E, three cases with Alcian Blue, three cases with PAS, and two cases with H. pylori. yy. 03/07/2024, 10 cases with H&E, five cases with Alcian Blue, one case with PAS, and four cases with H. pylori. zz. 03/19/2024, 22 cases with H&E, six cases with Alcian Blue, one case with PAS, and five cases with H. pylori. aaa. 04/04/2024, 12 cases with H&E, two cases with Alcian Blue, one case with PAS, and one case with H. pylori. bbb. 04/12/2024, 13 cases with H&E, three cases with Alcian Blue, one case with PAS, and two cases with H. pylori. ccc. 04/17/2024, six cases with H&E, three cases with Alcian Blue, two cases with PAS, and two cases with H. pylori. ddd. 04/19/2024, one case with GMS and PAS. eee. 04/24/2024, 20 cases with H&E, three cases with Alcian Blue, four cases with PAS, and three cases with H. pylori. fff. 05/21/2024, 12 cases with H&E, three cases with Alcian Blue, one case with PAS, and two cases with H. pylori. ggg. 05/26/2024, 15 cases with H&E, five cases with Alcian Blue, one case with PAS, and two cases with H. pylori. hhh. 06/04/2024, six cases with H&E, one case with Alcian Blue, one case with PAS, and one case with H. pylori. iii. 06/20/2024, 18 cases with H&E, four cases with Alcian Blue, two cases with PAS, and three cases with H. pylori. jjj. 06/24/2024, three cases with H&E, one case with Alcian Blue, one case with PAS, and one case with H. pylori. 5. An interview on 11/18/24 at 3:33 pm with the laboratory director confirmed control procedures had not been documented in accordance with laboratory procedure between November 2022 and November 2024.

D5475

CONTROL PROCEDURES
CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the laboratory director, the laboratory failed to perform and document positive and negative reactivity for its immunohistochemical testing each time of use for five of five total patients receiving testing between November 2022 and November 2024. Findings include: 1. A review of the laboratory's "Quality Control Stains IHC & Special Stains" policy revealed a

section stating, "Special stains and IHC controls are run along with patient samples daily. H&E controls are run daily to test the quality of the staining reagents; a supervising pathologist will view these slides before patient samples are stained. All controls will be archived for retrieval. Immunohistochemical and Special Stains will all be interpreted with the use of positive control stains and a negative control tissue stain. For all other differential or special stains, a control slide of know reactivity must be stained with each patient slide or group of patient slides. Positive control stains will be run for each patient group and will be labeled accordingly. A log will be kept that documents if the control slides are of acceptable quality." 2. A review of the laboratory's technical reference laboratory's list of cases processed prior to sending the specimen slides to the laboratory for reading titled "Sterling Pathology Daily Quality Control For Al-Midani" revealed a lack of documentation of immunohistochemical positive and negative reactivity each time of use staining for the following patient testing dates: a. 3/18/23 one patient had the following immunohistochemical stains: i. Pankeratin ii. Chromogranin iii. Synaptophysin iv. CD56 v. KI-67 b. 3/25/24 one patient had the following immunohistochemical stains: i. Chromogranin ii. Synaptophysin iii. CD56 iv. KI-67 c. 3/28/24 one patient had the following immunohistochemical stain: i. CD56 d. 4/19/24 one patient had the following immunohistochemical stains: i. CMV ii. HSV-1 iii. P53 e. 4/20/24 one patient had the following immunohistochemical stains: i. Chromogranin ii. Synaptophysin iii. P53 3. An interview on 11/18/24 at 3:33 pm with the laboratory director revealed the laboratory had used the reference laboratory's log that was submitted to the laboratory with the list of cases and stains prepared. The laboratory director confirmed control procedures had not been documented in accordance with laboratory procedure between November 2022 and November 2024.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
 . Based on record review and interviews, the laboratory director failed to ensure verification of accuracy testing of its histopathology testing was performed at least twice annually (refer to D6093 A), failed to ensure control procedures were performed and document for each date of patient testing for its routine and special stains (refer to D6093 B), failed to ensure control procedures were performed and documented for positive and negative reactivity for its immunohistochemical testing each time of use (refer to D6093 C), failed to ensure quality assessment programs were maintained (refer to D6094), and failed to follow its competency assessment policies to assess testing personnel competency (refer to D6103).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	<p>This STANDARD is not met as evidenced by:</p> <p>. A. Based on record review and interview with the laboratory director, the laboratory director failed to ensure verification of accuracy testing of its histopathology testing was performed at least twice annually. Refer to D5217. B. Based on record review and interview with the laboratory director, the laboratory director failed to ensure control procedures were performed and document for each date of patient testing for its routine and special stains. Refer to D5473. C. Based on record review and interview with the laboratory director, the laboratory director failed to ensure control procedures were performed and documented for positive and negative reactivity for its immunohistochemical testing each time of use. Refer to D5475.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review and interview with the laboratory director, the laboratory director failed to ensure quality assessment programs were maintained for two (November 2022 to November 2024) of two years reviewed. 1. A review of the laboratory's "General Lab Quality Assurance Policy" revealed a section stating, "Performance improvement is an ongoing continuous process and fulfills the lab's mission" and "Activities covered by the QA Plan: Accuracy, Precision, Results Reporting, Critical values reporting, and Patient's safety." 2. An interview on 11/18/24 at 2:25 pm with the laboratory director revealed documentation of the laboratory's quality assessment activities from November 2022 to November 2024 were not present.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review and interview with the laboratory director, the laboratory director failed to follow its competency assessment policies to assess testing personnel competency. Refer to D5209.</p>