Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2283231	01/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sbmf/Ascension Borgess	1521 Gull Road 1st Floor Histology, Kalamazoo, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Quality Systems Manager, the laboratory failed to operate as a separate laboratory to comply with 493. 43 for 7 (July 2023 to January 2024) of 7 months since the laboratory began operations. Findings include: 1. The surveyor observed the laboratory testing area is located within the greater histology section of the 23D0376741 Ascension Borgess Hospital laboratory on 1/29/24 at 9:22 am. 2. A review of the laboratory's temperature and stain logs revealed the same logs were used to document these activities for the 23D0376741 Ascension Borgess Hospital laboratory. 3. A review of the laboratory's patient test reports revealed 23D0376741 Ascension Borgess Hospital laboratory was indicated as the laboratory performing testing. 4. A review of the laboratory's Form CMS-116 revealed the laboratory operates Monday-Friday 8:00 am to 4:00 pm. 5. An interview on 1/29/24 at 11:36 am with the Quality Systems Manager revealed the 23D0376741 Ascension Borgess Hospital laboratory operates 24 hours a day, 7 days a week, confirming the laboratories are testing concurrently.
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, record review, and interview with the Quality Systems Manager, the laboratory failed to ensure its tissue marking dyes and coverslipping medium had not exceeded expiration dates for 5 of 8 tissue marking dyes and coverslipping medium bottles observed. Findings include: 1. A review of the laboratory's "Frozen Section Room and Cryostat Cleaning" procedure revealed a section stating, "Check expiration dates and replace reagents as needed." 2. The surveyor observed three bottles of the laboratory's Cytoseal coverslipping medium on 1/29/24 at 9:26 am. Two of the three bottles had an expiration date of "10/2021" listed on the bottles. 3. The surveyor observed five bottles of the laboratory's tissue marking dyes on 1/29/24 at 9:31 am. Two of the five bottles had been expired on 5/31/23 and 7 /31/23. 4. An interview on 1/29/24 at 9:31 am with the Quality Systems Manager confirmed the above supplies had exceeded expiration dates.
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 Quality Systems Manager, the laboratory failed to assess and document hematoxylin and eosin staining materials for predictable staining characteristics for 6 (July 2023 to January 2024) of 6 months reviewed. Findings include: 1. The surveyor requested documentation of stain quality assessments each date of patient testing on 1/26/24 at 11:31 am and it was not made available. 2. An interview on 1/26/24 at 11:31 am with the Quality Systems Manager confirmed documentation of stain quality assessments were not present.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Systems Manager, the testing personnel performing frozen section histopathology examinations failed to sign pathology test reports for 2 (Patient #1 and #4) of 6 patient test reports reviewed. Findings include: 1. A review of frozen section histopathology test reports revealed a lack of signature of testing personnel for the following patient test reports: a. Patient #1 with testing performed on 12/13/23. b. Patient #4 with testing performed on 9/26 /23. 2. An interview on 1/29/24 at 11:19 am with the Quality Systems Manager confirmed the signature of testing personnel performing the frozen section histopathology examinations was not present for the patient test reports listed above.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Systems Manager, the laboratory failed to include the name and address of the laboratory location where testing was performed for 6 (Patients 1-6) of 6 patient test reports reviewed. Findings include: 1. A review of the laboratory's Form CMS-116 revealed the name of the laboratory is "SBMF/Ascension Borgess" and the address is "1521 Gull Rd 1st floor histology Kalamazoo, MI 49048." 2. A review of patient test reports revealed the laboratory name listed was "Ascension Borgess Hospital Department of Pathology" and the address as "1521 Gull Road Kalamazoo, MI 49048-1666" for the following patients with frozen section histopathology testing performed: a. Patient #1 had testing performed on 12/20/23. b. Patient #2 had testing performed on 11/9/23. c. Patient #3 had testing performed on 10/6/23. d. Patient #4 had testing performed on 9/26/23. e. Patient #5 had testing performed on 8/7/23. f. Patient #6 had testing performed on 7/19 /23. 3. An interview on 1/29/24 at 11:40 am with the Quality Systems Manager confirmed the laboratory name and address listed on the patient test reports listed above was not for the laboratory where frozen section histopathology testing was performed.