

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2174160	(X3) Date Survey Completed 09/20/2021
Name of Provider or Supplier Memorial Ambulatory Surgery Center	Street Address, City, State 8731 Katy Freeway, Suite 400, Houston, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a random review of patient test records, a review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to document the negative and positive reactivity of quality control slides for the hematoxylin and eosin (H&E) stain each day of patient testing for two of eight days reviewed between January 2021 and August 2021. Findings include: 1. A random review of patient test records between January 2021 and August 2021 revealed the following two patient's specimens were tested using H&E stain on the dates listed below: a) January 25, 2021 Case number: SB-21-00472 b) August 18, 2021 Case number: SB-21-05605 2. A review of the laboratory's quality control records revealed there was no documentation of the negative and positive reactivity of quality control slides for the H&E stain on the dates listed above. 3. An interview with the lead business strategy and development co-chair on 9/20/21 at 2:50 p.m. in the laboratory, after review of the records, confirmed the above findings.</p>

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to ensure three of four testing personnel had documentation of training to perform high complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 9/16/21) revealed the laboratory identified four testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed the following three testing personnel failed to have documentation of training for performing high complexity testing in the specialty of Histopathology: Testing person #2 Testing person #3 Testing person #4 3. An interview with the lead business strategy and development co-chair on 9/20/21 at 2:15 p.m. in the laboratory, after review of the records, confirmed the above findings.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the laboratory failed to have documentation of the technical supervisor performing competency assessments at least semiannually during the first year of testing in 2020 and 2021, on two of four testing personnel performing high complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified four testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical supervisor performing competency assessments at least semiannually during the first year of testing for the following two testing personnel performing high complexity testing: Testing person # 2 - hire date 1/17/20 - competency assessment performed 11/2/20 - no documentation of a second competency assessment prior to 1/2021 Testing Person # 3 - hire date 1/17/20 - competency assessment performed 11/2/20 - no documentation of a second competency assessment prior to 1/2021 3. An interview with the lead business strategy and development co-chair on 9/20/21 at 2:10 p.m. in the laboratory, after review of the records, confirmed the above findings.