

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0327580	(X3) Date Survey Completed 06/06/2023
Name of Provider or Supplier Medical And Surgical Associates	Street Address, City, State 1930 Tamarack Rd, Newark, OH	
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
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interviews with Technical Consultant (TC) #1 and Testing Personnel (TP) #1, the laboratory failed to ensure test requisition information, including the date and time of specimen collection, was transcribed accurately into the laboratory information system. This deficient practice affected a sample of 164 out of 167 patients tested in specialties of hematology and chemistry from April and May 2022 and April, May and June 2023. Findings Include: 1. Review of the laboratory's Specimen Rejection and Handling policy found the following statement: "... Specimens must be accessioned, (identified and logged); properly labeled with the patient's complete name and secondary identifier, date and time of collection, and initials of phlebotomist. A label generated by the laboratory information system (LIS) or electronic medical record (EMR) that contains the verified identification information serves as proper labeling..." 2. The surveyor reviewed a sample of 13 requisitions and corresponding final test reports. The surveyor found a collection time handwritten by the phlebotomist on the top of the requisitions. The surveyor noted that the sticker on the requisition indicated the time the order was entered into the laboratory information system which populated on the final test report instead of the collect time. Patient 1 Handwritten collection time: 753 Sticker collection time: 8:12 AM Final report collection time: 8:12 AM Final report specimen received time: 8:12 AM Patient 2 Handwritten collection time: 747 Sticker collection time: 8:13 AM Final report collection time: 8:13 AM Final report specimen received time: 8:13 AM Patient 3 Handwritten collection time: 744 Sticker collection time: 8:24 AM Final report collection time: 8:24 AM Final report specimen received time: 8:24 AM Patient 4</p>

Handwritten collection time: 8:30 Sticker collection time: 3:02 PM Final report collection time: 8:12 AM Final report specimen received time: 8:12 AM Patient 5
 Handwritten collection time: [none] Sticker collection time: 11:27 AM Final report collection time: 11:27 AM Final report specimen received time: 11:27 AM Patient 6
 Handwritten collection time: 9:00 Sticker collection time: 9:02 AM Final report collection time: 9:05 AM Final report specimen received time: 9:05 AM Patient 7
 Handwritten collection time: 8:30 Sticker collection time: 9:22 AM Final report collection time: 9:22 AM Final report specimen received time: 9:22 AM Patient 8
 Handwritten collection time: 9:12 Sticker collection time: 9:23 AM Final report collection time: 9:23 AM Final report specimen received time: 9:23 AM Patient 9
 Handwritten collection time: 9:18 Sticker collection time: 9:25 AM Final report collection time: 9:25 AM Final report specimen received time: 9:25 AM Patient 10
 Handwritten collection time: 8:50 Sticker collection time: 9:27 AM Final report collection time: 9:27 AM Final report specimen received time: 9:27 AM Patient 11
 Handwritten collection time: 8:45 Sticker collection time: 9:28 AM Final report collection time: 9:28 AM Final report specimen received time: 9:28 AM Patient 12
 Handwritten collection time: 9:24 Sticker collection time: 9:29 AM Final report collection time: 9:29 AM Final report specimen received time: 9:29 AM Patient 13
 Handwritten collection time: 9:30 Sticker collection time: 9:39 AM Final report collection time: 9:39 AM Final report specimen received time: 9:39 AM 3. The surveyor reviewed an additional 154 final patient test reports for a total of 167. The surveyor found that 164 out of 167 had the same collection time and received time on the final test report. 4. A telephone conversation with TP #1 on 06/08/2023 at 12:05 PM confirmed that the laboratory failed to ensure test requisition information, included the accurate date and time of specimen collection, was transcribed accurately into the laboratory information system per the policy. 5. An email with TC #1 on 06/08/2023 at 4:12 PM confirmed that the laboratory failed to ensure test requisition information, included the accurate date and time of specimen collection, was transcribed accurately into the laboratory information system per the policy.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
 CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Item I: Based on record review, direct observation, and an interview with Testing Personnel (TP) #1, the laboratory failed to follow written policies and procedures for documentation of specimen acceptability and rejection. This deficient practice had the potential to affect 315,685 out of 315,685 patients tested annually at this laboratory in the specialties of chemistry and hematology. Findings Include: 1. Review of the laboratory's Specimen Rejection policy on 06/06/2023 at 10:43 AM found the following statements: "Rejected specimens may include: ...3. Information on specimen does not match information on requisition..." "...Documentation must be made in the specimen rejection log..." 2. Review of the laboratory's Specimen Rejection Log on 06/06/2023 at 10:43 AM found it to be blank. 3. On 06/06/2023 at 1:43 PM the surveyor observed a specimen enter the laboratory for processing. TP #1

noted that the date of birth on specimen did not match the date of birth on the requisition. TP #1 notified appropriate staff and rectified the error. 4. An interview with TP #1 on 06/06/2023 at 4:25 PM confirmed that the laboratory failed to document the error on the Specimen Rejection Log. Item II: Based on record review and interviews with the Technical Consultant (TC) #1 and Testing Personnel (TP) #1, the laboratory failed to follow written policies and procedures for specimen collection requirements in the specialty of chemistry. This deficient practice had the potential to affect one out of 3471 patients tested in the specialty of chemistry from January through March of 2023. Findings Include: 1. Review of the Blood Collection policy found the following statement: "...The phlebotomist must possess knowledge of laboratory tests to include references for or knowledge of proper collection volumes, specific collection tubes for specific tests, and as well as the knowledge to process samples according to the protocol of the specific test methodology..." 2. Review of the Specimen Collection, Handling and Transport policy found the following statement: "...Specimen collection personnel will... ..obtain appropriate specimen..." 3. Review of the Specimen Rejection policy found the following statement: "...Rejected specimens may include: ...c. Improper specimen for requested test, ie: not collected in the proper container or tube..." 4. Review of the Specimen Collection, Handling and Transport policy found a table that included a list of the types of blood collection tubes and their uses within the laboratory: 5. Review of the final test report of the patient in question found the following statement: "...Test not performed. Sample contaminated with EDTA which is not suitable for test ordered. TEST: 322000 Comp. Metabolic Panel (14)..." 6. An interview with TC #1 on 06/06/2023 at 4:25 PM confirmed that TP #1 contacted them immediately regarding the unusual result. The TC #1 confirmed that TP #1 will contact the TC with any result that is unusual. One out of 3,471 patients had the potential to be affected by this deficient practice from January to March of 2023.