

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468881	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier Mana Family Medicine Springdale	Street Address, City, State 1109 S West End Street, Springdale, AR	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency testing attestation sheets for 2021 and 2022, a review of patient results and through interviews with laboratory staff, it was determined one of two testing personnel who perform patient testing, did not perform proficiency testing. Survey findings include: A) The laboratory retains attestation sheets for each proficiency testing event. The attestations are signed by testing personnel and laboratory director as documentation that the testing was performed in the same manner as patient samples. The laboratory performed proficiency testing in three testing events in 2021 and three testing event in 2022. All attestation sheets for 2021 and 2022 were signed by laboratory employee #3 (as listed on the form CMS-209) except for the second testing even in 2021 on which there were no signatures on the attestation form. Laboratory employee #4 never attested to performing proficiency testing during 2021 and 2022 (six events). B) Review of patient results for CBC testing performed in November 2022 revealed that the testing personnel (#4 on the CMS 209 form) performed and reported 13 CBC tests. C) In an interview, at 4:05 p. m.. on 12/6/22, laboratory employee #3 confirmed that she was the only laboratory employee performing proficiency testing.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the</p>

laboratory's routine methods.

This STANDARD is not met as evidenced by:

Through a review of documentation for the six proficiency testing events completed by the laboratory in 2021 and 2022, lack of documentation, and interviews with staff, it was determined the laboratory testing personnel and director failed to sign the attestation statements for one of six proficiency testing events completed by the laboratory. Survey findings include: A) A review of the proficiency test documentation for 2021 revealed the laboratory performed proficiency testing API Hematology/Coagulation event #2 and the attestations for the event was not signed by the testing personnel or the laboratory director or designee. B) Laboratory employee (#3 on the CMS 209 form) confirmed, in an interview at 4:05 p.m. on 12/6/22, that the attestation form lacked the required signatures.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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:

Through review of the CMS 209 form, personnel records, and the plan of correction submitted for the survey conducted on 11/17/2020 it was determined that the competency of the technical consultant was not assessed by the laboratory director on an annual basis. This deficiency was cited on the prior survey conducted on 11/17/2020. Findings follow: A) Review of personnel files revealed that the annual evaluation of the competency of the technical consultant (number two on the CMS 209 form) was documented only once dated 12/14/20 and no other documentation of technical consultant competency was presented, B) Upon request, the laboratory was unable to provide other competency evaluations of the technical consultant (number two on the CMS 209 form) subsequent to the evaluation identified above. C) Review of the plan of correction submitted for the same deficiency cited on the survey conducted on 11/17/2020 revealed that the competency evaluation for the technical consultant (number two on the CMS 209 form) was dated with the identical date and appeared identical in every way as the evaluation presented for the current survey D) In an interview on 12/6/22 at 10:30 a.m. the testing personnel (number three on the CMS 209 form) said that no other competency evaluations for the technical consultant were present and available. .