

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0366080	(X3) Date Survey Completed 01/11/2022
Name of Provider or Supplier Mhp DbA South Macomb Internists	Street Address, City, State 11885 E 12 Mile Road #100b, Warren, 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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the Technical Consultant failed to assess testing personnel competency at least semiannually during their first year testing Complete Blood Count (CBC) specimens for 1 (Testing Personnel #2) of 2 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the competency assessments for Testing Personnel #2 revealed Testing Personnel #2 was trained to perform CBC testing on 3/30/20 and had competency assessed on 9/24/20 and 9/20/21. 2. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a section stating, "Laboratory compliance requires training/competency to be completed initially, 6-months after the initial start date and annually thereafter." 3. An interview with TC on 1/11/22 at 11:30 am confirmed the laboratory performs the training checklist with the testing personnel, then performs a competency assessment 6 months after training, then performs another competency assessment a year later.</p>
D6094	<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>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the Laboratory Director failed to ensure the specimen handling component of the laboratory's quality assessment program was performed for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "South Macomb Internists" procedure revealed a section stating, "A random access of 10 samples are checked for correctness of specimen handling quarterly. That includes identification and labeling of test tubes, correct data in computer, handling and storage of samples, documentation of unacceptable specimens and reporting and resulting patient." Next to "correct data in computer" has "reviewed under test tracking" written. Next to "reporting and resulting patient" has "reviewed under post testing phase" written. 2. The surveyor requested documentation on 1/11/22 at 10:57 am showing the review of 10 samples checked for the correctness of specimen handling quarterly and it was not made available. 3. An interview on 1/11/22 at 10:57 am with the TC confirmed the laboratory does not perform and record a review of 10 samples for correctness of specimen handling quarterly.