

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2035129	<b>(X3) Date Survey Completed</b>  12/05/2019
<b>Name of Provider or Supplier</b>  Corewell Health Reference Laboratory West	<b>Street Address, City, State</b>  35 Michigan Street Ne, Grand Rapids, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review, procedure review, and interview, the laboratory submitted proficiency testing samples to another facility for testing. Proficiency testing specimens were submitted to 23D0380113 Spectrum Health Butterworth Hospital Laboratory (SH Butterworth) for sickle screening for 4 (HG-A and HG-B 2018 and 2019) of 4 testing events. SH Regional laboratory reported SH Butterworth results for 3 (HG-A and HG-B 2018 and HG-A 2019) of 4 final proficiency testing (PT) results to the PT provider College of American Pathologist (CAP) as their own. Refer to D2013.</p>
<b>D2013</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency</p>

testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

. Based on document review, procedure review, and interview with the Senior Director of Laboratory (SDL) and the Laboratory Director (LD), Spectrum Health Regional Laboratory (SH Regional) 1) submitted proficiency testing (PT) samples for sickle cell screen testing to 23D0380113 Spectrum Health Butterworth Hospital Laboratory (SH Butterworth) for 4 (HG-A and HG-B in 2018 and 2019) of 4 testing events reviewed; and 2) SH Regional laboratory reported SH Butterworth's results as their own for 3 (HG-A and HG-B 2018 and HG-A 2019) of 4 PT testing events reviewed to the PT provider College of American Pathologists (CAP). Findings include: 1. In a letter sent to Michigan Department of Licensing and Regulatory Affairs (LARA) dated September 6, 2019, signed by the LD stated the following: a. On page 1, the second paragraph, "We recently became aware that the Butterworth Lab received a proficiency testing ("PT") sample from the Regional Lab on August 15, 2019 for Hemoglobin S Solubility Testing for sickle cell analysis. The Regional Lab does not have the capability to perform such testing and these tests are not included on our test menu with the College of American Pathologists. The Regional Lab routinely refers such testing to the Butterworth Lab for testing. Butterworth Lab personnel contacted the Regional Lab and questioned receipt of the PT sample and did not conduct the analysis" b. On page 1, the third paragraph, "Given that the Regional Lab lacks this capability and these tests should not have been included in the Regional Lab's test menu, the PT results should have been marked "NA" for this testing." c. On page 2, the second to last paragraph, "We have also conducted a review of all laboratory testing for the previous two (2) years to determine whether any other PT samples were referred by the Regional Lab to any other lab. Our investigation revealed that PT samples were sent to the Butterworth Lab on three (3) other occasions and testing and the testing results were reported to CAP by the Regional Lab." 2. Review of a letter sent to CAP dated September 11, 2019, signed by the LD stated the following: a. On page 3, response to CAP question #4, "The Regional Lab conducted a two year look-back and determined that Hemoglobin S Solubility Testing PT samples were transferred like patient specimens on three other occasions to the Butterworth Lab. The PT samples were tested by the Butterworth Lab for sickle cell analysis on three separate occasions. Below is a direct reference to the identified three occasions. HG A 2019 - 4 samples tested and reported by March 5, 2019 HG B 2018 - 4 samples tested and reported by September 4, 2018 HG A 2018 - 4 samples tested and reported by March 6, 2018." 3. Record review of the SH Regional CAP proficiency testing final graded reports revealed results for 3 (HG-A and HG-B for 2018 and HG-A for 2019) of 4 testing events reviewed for "sickling test" as follows: a. HG - A 2018 CAP HG-01 - negative CAP HG-02 - negative CAP HG-03 - negative CAP HG-04 - negative b. HG - B 2018 CAP HG-07 - positive CAP HG-08 - negative CAP HG-09 - negative CAP HG-10 - negative c. HG - A 2019 CAP HG-01 - negative CAP HG-02 - negative CAP HG-03 - negative CAP HG-04 - negative 4. Record

review of the CAP proficiency testing attestation sheets revealed for 3 (HG-A and HG-B for 2018 and HG-A for 2019) of 4 testing events reviewed, staff from SH Butterworth signed the SH Regional PT attestation. a. HG-A 2018 -The attestation statement sheet for SH Regional shows testing personnel #1 (TP1) from SH Butterworth performed testing. b. HG-B 2018 - The attestation statement sheet for SH Regional shows testing personnel #4 (TP4) from SH Butterworth performed testing. c. HG-A 2019 - The attestation statement sheet for SH Regional shows testing personnel #3 (TP3) from the SH Butterworth performed testing. 5. Procedure review for "Hemoglobin Fractionation (Biorad Variant II) under Section D "Running Quality Control and Patients" Step 15 b. states "If a patient has a hemoglobin S peak and is not a known S hemoglobin patient, have a Sickel Screen run on the specimen. Order a sickle cell screen send sample to SH Butterworth for testing and note results of the test on the fractionation printout for the pathologist to review." 6. Record review of the SH Regional CAP proficiency testing final graded reports revealed for the 3 (HG-A and HG-B for 2018 and HG-A for 2019) testing events that SH Regional submitted "sickling test" results, the following samples had a hemoglobin S identified and quantified: a. HG - A 2018 No samples b. HG - B 2018 CAP HG-07 c. HG - A 2019 No samples 7. Procedure review for "Proficiency Testing Policy" under Section B "Analysis of Proficiency testing Samples" Step 4 states "Proficiency test samples or portions of the sample must not be sent to another laboratory for analysis, or be accepted from another laboratory." 8. Procedure review for "Proficiency Testing Policy" under Section C "Proficiency Testing Results" Step 1 states "Proficiency testing results must not be sent to any other laboratory location (including different sites within the Spectrum Health system) until after the deadline for submission, as indicated on the survey form, has passed." 9. During the interview on 12/5/19 at approximately 10:00 a.m., the SDL and LD confirmed SH Regional laboratory submitted PT specimens to SH Butterworth for sickle screen testing and SH Butterworth results were submitted to CAP the PT provider.