

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0380113	(X3) Date Survey Completed 12/05/2019
Name of Provider or Supplier Corewell Health Butterworth Hospital Laboratory	Street Address, City, State 100 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<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, Spectrum Health Butterworth Hospital Laboratory (SH Butterworth) received proficiency testing samples from another facility for the College of American Pathology proficiency testing events HG- A and HG-B in 2018 and 2019. Refer to D2011 and D2013.</p>
D2011	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.</p>

This STANDARD is not met as evidenced by:
. Based on procedure review, record review, and interview with the Senior Laboratory Director (SDL) and the Laboratory Director (LD), the laboratory engaged in inter-laboratory communication with another laboratory prior to the proficiency testing (PT) submission date for 3 (HG A 2019, HG B 2018, and HG A 2018) of 4 testing events. Findings include: 1. Review of the procedure "Proficiency Testing Policy" version #4, effective date 08/04/2017 states in section C, number 2 "The performing laboratory will not engage in any interlaboratory communications pertaining to the results of the proficiency testing samples until after the date by which the results are reported to the proficiency testing program." 2. Record review of the PT documents for 3 of 4 testing events revealed 23D0380113 Spectrum Health Butterworth Hospital Laboratory and 23D2035129 Spectrum Health Regional Laboratory had engaged in laboratory communications by the exchanging of the PT testing kits and the results for the sickle cell screening as follows: a. HG A 2019 b. HG B 2018 c. HG A 2018 3. During the interview on 12/5/19 at approximately 10:30 a.m., SDL and LD confirmed the sickle screen proficiency testing samples were received from 23D2035129 Spectrum Health Regional Laboratory for 4 of 4 testing events in 2018 and 2019, testing was performed and results returned to the sending laboratory for 3 (HG-A and HG-B 2018 and HG-A 2019) of 4 events.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(4)

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 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 record review, procedure review, and interview with the Senior Director of Laboratory (SDL) and the Laboratory Director (LD), the laboratory received proficiency testing samples for 4 (HG-A and HG-B in 2018 and 2019) of 4 testing events for sickle screening from 23D2035129 Spectrum Health Regional Laboratory (SH Regional). The laboratory tested and returned PT results for sickle screen testing to SH Regional for 3 (HG-A and HG-B 2018 and HG-A 2019) of 4 testing events reviewed 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 first paragraph, "Please allow this correspondence to service as notice of receipt by Spectrum Health Butterworth Hospital Laboratory ("Butterworth Lab"), CLIA 23D0380113, of receipt of proficiency testing samples

from Spectrum Health Regional Laboratory ("Regional Lab"). CLIA 23D2035129" b. 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 of performing such testing and routinely refers such testing to the Butterworth Lab for testing. Butterworth Lab personnel questioned receipt of the PT sample and did not conduct the analysis" c. On page 1, 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 received by the Butterworth Lab. Our investigation revealed that PT samples were received on three (3) other occasions and testing was conducted on the samples." 2. Review of a letter sent to CAP dated September 11, 2019, signed by the LD stated the following: a. On page 2, response to CAP question #2, "Butterworth lab questioned receipt of the PT sample before any testing of the sample occurred and immediately notified a supervisor. No analysis, interpretation or testing occurred on the sample and no results were thus reported back to the Regional Lab or reported to the PT provider." b. On page 2, response to CAP question #3, "The Butterworth Lab conducted a review of laboratory testing for the previous two (2) years to determine whether any other PT samples were received by the Butterworth Lab. Our investigation revealed that on three other occasions (two in 2018 and one in 2019), PT samples were received at the Butterworth Lab from the Regional Lab that were tested for sickle cell. The former lead employee who oversaw the Hemoglobin S Solubility for sickle cell analysis is no longer employed by the Butterworth Lab (retired early 2019). 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." c. On page 2, response to CAP question #4, "The Butterworth Lab is not enrolled in the same HG proficiency survey. Butterworth Lab is enrolled in API Sickle Cell Testing for 2019 and CAP Sickle Cell Testing for 2018." 3. Review of "Spectrum Health Blood Bank Sickle Cell Test Log" reveals that on 2-16-18 testing on CAP HG-01, CAP HG-02, CAP HG-03, and CAP HG-04 were performed and all results were negative by testing personnel #1 (TP1). 4. Review of "Spectrum Health Blood Bank Sickle Cell Test Log" reveals that on 2-14-19 testing on HG-01, HG-02, HG-03, and HG-04 were performed and all results were negative by testing personnel #3 (TP3). 5. Record review of the SH Regional CAP proficiency testing attestation sheets revealed for 3 (HG-A and HG-B for 2018 and HG-A for 2019) testing events 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 the 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. 6. 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." 7. 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." 8. During the interview on 12/5/19 at approximately 10:30 a.m., SDL and LD confirmed the sickle screen proficiency testing samples were received from 23D2035129 Spectrum Health Regional Laboratory for 4 of 4 testing events in 2018 and 2019, testing was performed and results returned to the sending laboratory for 3 (HG-A and HG-B 2018 and HG-A 2019) of 4 events.