

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0993420	(X3) Date Survey Completed 04/11/2019
Name of Provider or Supplier Egret Cove Center	Street Address, City, State 550 62nd St South, Saint Petersburg, FL	
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
D0000	An unannounced complaint survey, #2019002975, was conducted on 04/10/19 to 04/11/19 at Egret Cove Center. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. During the complaint survey, the laboratory was found out of compliance with the following condition at the Immediate Jeopardy level: 42 CFR 493.1771 Inspection Requirements Immediate Jeopardy was identified as beginning on 04/10/19 and was abated 04/11/19.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observations, record review, and staff interview, the facility failed to assure compliance with the requirement for following manufacturer's instruction for glucometers used for testing glucose levels on insulin dependent patients for an undetermined amount of time. Findings Included: 1. Review of the manufacturer's instructions revealed that the Evencare G2 glucose control solutions should be stored at 59-86 degrees Fahrenheit, the blood glucose test strips should be stored between 39-86 degrees Fahrenheit, and the glucose meter should be stored at 50-104 degrees Fahrenheit and less than 85% humidity. During a tour of the facility on 04/10/19 at 1:15 PM the following was observed: 1 glucometer on a medication cart on South 100 Hall with 2 bottles of test strips opened 03/31/19 and 04/01/19, 2 glucometers on a medication cart on South 200 Hall with 1 bottle of test strips opened 03/31/19, 2 glucometers on a medication cart on North 300 Hall with 1 bottle of test strips opened 04/03/19, and 2 glucometers on a medication cart on North 400 Hall with 1 bottle of test strips opened on 04/10/19. There was also 3 unopened glucometers, 10 boxes of unopened test strips, and 1 unopened box of quality control (QC) in a cabinet in</p>

central supply. No temperature or humidity device was observed at any of the locations. Interview on 04/10/19 at 1:30 PM with Licensed Practical Nurse (LPN) #A stated that they do not monitor the temperature or humidity of the drawers where the meters and test strips were stored. Interview on 04/10/19 at 1:45 PM with the Director of Nursing (DON) confirmed that the temperature or humidity of all 5 locations were not documented. 2. Review of the manufacturer's instructions revealed that controls should be performed when opening a new bottle of test strips "to make sure the Evencare G2 Meter [glucometer] and the Evencare G2 Test Strips are working properly." During a tour of the facility on 04/10/19 at 1:15 PM 5 opened bottles of test strips were observed: #1-opened 03/31/19, #2- opened 04/01/19, #3- opened 03/31/19, #4- opened 04/03/19, and #5- opened 04/10/19. Test strip #1 and #2 were on South 100 Hall and QC was performed on 03/20/19 and 04/10/19. Test strip #3 was on South 200 Hall and QC was performed on 03/28/19 and 04/01/19. Test strip #4 was on North 300 Hall and QC was performed 03/30/19 and 04/07/19. Test strip #5 was on North 400 Hall and QC was performed 04/09/19. None of the 5 open test strip bottles had QC performed on the date opened per manufacturer's instruction. Interview on 04/10/19 at 2:30 PM the DON confirmed that the facility uses the manufacturer's instructions for the policy for glucometer testing and confirmed the staff did not perform QC when they opened they 5 bottles of test strips. 3. Review of the Manufacturer's Instructions for glucose control solutions (Revision 01/18) revealed that "The purpose of the control solution is to validate the performance of the EVENCARE G2 Blood Glucose Monitoring System using a testing solution with a known range of glucose. A control test that falls with the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly." It also states "If results continue to be out of range after all instructions have been followed, the system is not functioning properly. DO NOT use the system to test your blood glucose until you get a reading that is within the acceptable range." QC logs were reviewed from February 2019, March 2019, and April 2019. The DON confirmed on 04/10/19 at 1:00 PM that there are 2 glucometers per cart being used. In the South 100 Hall, glucometer #1 did not have a QC log for February 2019, and glucometer #2 did not have QC logs for February 2019, March 2019, or April 2019. In the South 100 Hall, glucometer #1 had 1 control on March 20, 2019 and 1 on April 10, 2019 that was in range. Acceptable limits for low range is 37-67 mg/dL and high range is 158-214 mg/dL. In the South 200 Hall, glucometer #1 had 7 out of 7 (2/15=26, 2/18=20, 2/19=22, 2/20=20, 2/21=24, 2/22=20, 2/25=22) days QC performed the low level control was not acceptable in February 2019. In the South 200 Hall, glucometer #2 had 7 out of 7 (2/15=22, 2/18=34, 2/19=20, 2/20=22, 2/21=20, 2/22=21, 2/25=24) days QC performed the low level control was not acceptable in February 2019. In the South 200 Hall glucometer #1 had 21 out of 21 (3/1=23, 3/4=20, 3/5=22, 3/6=24, 3/7=21, 3/8=26, 3/11=20, 3/12=23, 3/13=21, 3/14=22, 3/15=20, 3/18=24, 3/19=20, 3/20=19, 3/21=21, 3/22=20, 3/23=20, 3/25=22, 3/26=20, 3/27=19, and 3/28=20) days and #2 had 13 out of 13 (3/1=20, 3/4=24, 3/5=22, 3/6=21, 3/18=23, 3/19=20, 3/20=24, 3/21=22, 3/22=20, 3/25=20, 3/26=19, 3/27=22, and 3/28=20) days QC performed the low level control was not acceptable in March 2019. In the South 200 Hall glucometer #1 had 2 out of 2 (4/1=20 and 4/2=19) days QC performed the low level control was not acceptable in April 2019. In the South 200 Hall glucometer #2 had 2 out of 2 (4/1=20 and 4/2=20) days QC performed the low level control was not acceptable in April 2019. In the North 300 Hall there was no QC log for glucometer #1 or #2 in February 2019. In the North 300 Hall glucometer #1 there was 2 (3/25=225 and 3/27=218) out of 8 (3/2, 3/3, 3/24, 3/25, 3/26, 3/27, 3/28, and 3/30) days QC performed the high level control was not acceptable in March 2019. In the North 300 Hall glucometer #2 was not in use March 2019. In the North 300 Hall for glucometer #1 had QC done on April 7, 8, 9, and 10 within range in

2019. In the North 300 Hall glucometer #2 did not have a QC log. In the North 400 Hall glucometer #1 had 1 (2/20=239) out of 9 (2/17, 2/18, 2/19, 2/20, 2/24, 2/25, 2/26, and 2/27) days the high level control was not acceptable in February 2019. In the North 400 Hall glucometer #2 had 5 out of 5 (2/17, 2/18, 2/20 [7-3 shift], 2/20 [11-7 shift], and 2/23) that were acceptable in February 2019. In North 400 Hall glucometer #1 and #2 did not have a QC log for March 2019. In the North 400 Hall glucometer #1 did not have a QC log for April 2019. In the North 400 Hall glucometer #2 had 16 out of 16 (4/2 [6 AM], 4/2[11-7 shift], 4/3[6 AM], 4/3[11-7 shift], 4/4[6 AM], 4/4[11-7 shift], 4/5[6 AM], 4/5[11-7 shift], 4/6[6 AM], 4/6[11-7 shift], 4/7[6 AM], 4/7[11-7 shift], 4/8[6 AM], 4/8[11-7 shift], 4/9[6 AM] and 4/9[11-7 shift]) days of QC acceptable. On 04/10/19 at 3:13 PM, the DON stated that he could not find any of the missing logs and that the nurses on the different halls were supposed to let him know when the controls were not acceptable and confirmed that he had not been contacted. Seventeen current patients were receiving insulin based on the result of the glucose test at the time of the survey.

D8100

INSPECTION REQUIREMENTS
CFR(s): 493.1771

Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:
Based on observations, record review, and staff interview, the facility failed to meet the requirement for following manufacturer's instructions for blood glucose monitoring system testing used for insulin dependent patients as required under a Certificate of Waiver for an undetermined amount of time (See D8201).

D8201

INSPECTION OF COW OR PPMP LABS
CFR(s): 493.1775(b)

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following:
(b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

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Fahrenheit and less than 85% humidity. During a tour of the facility on 04/10/19 at 1:15 PM the following was observed: 1 glucometer on a medication cart on South 100 Hall with 2 bottles of test strips opened 03/31/19 and 04/01/19, 2 glucometers on a medication cart on South 200 Hall with 1 bottle of test strips opened 03/31/19, 2 glucometers on a medication cart on North 300 Hall with 1 bottle of test strips opened 04/03/19, and 2 glucometers on a medication cart on North 400 Hall with 1 bottle of test strips opened on 04/10/19. There was also 3 unopened glucometers, 10 boxes of unopened test strips, and 1 unopened box of quality control (QC) in a cabinet in central supply. No temperature or humidity device was observed at any of the locations. Interview on 04/10/19 at 1:30 PM with Licensed Practical Nurse (LPN) #A stated that they do not monitor the temperature or humidity of the drawers where the meters and test strips were stored. Interview on 04/10/19 at 1:45 PM with the Director of Nursing (DON) confirmed that the temperature or humidity of all 5 locations were not documented.

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3. Review of the Manufacturer's Instructions for glucose control solutions (Revision 01/18) revealed that "The purpose of the control solution is to validate the performance of the EVENCARE G2 Blood Glucose Monitoring System using a testing solution with a known range of glucose. A control test that falls with the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly." It also states "If results continue to be out of range after all instructions have been followed, the system is not functioning properly. DO NOT use the system to test your blood glucose until you get a reading that is within the acceptable range." QC logs were reviewed from February 2019, March 2019, and April 2019. The DON confirmed on 04/10/19 at 1:00 PM that there are 2 glucometers per cart being used. In the South 100 Hall, glucometer #1 did not have a QC log for February 2019, and glucometer #2 did not have QC logs for February 2019, March 2019, or April 2019. In the South 100 Hall, glucometer #1 had 1 control on March 20, 2019 and 1 on April 10, 2019 that was in range. Acceptable limits for low range is 37-67 mg/dL and high range is 158-214 mg/dL. In the South 200 Hall, glucometer #1 had 7 out of 7 (2/15=26, 2/18=20, 2/19=22, 2/20=20, 2/21=24, 2/22=20, 2/25=22) days QC performed the low level control was not acceptable in February 2019. In the South 200 Hall, glucometer #2 had 7 out of 7 (2/15=22, 2/18=34, 2/19=20, 2/20=22, 2/21=20, 2/22=21, 2/25=24) days QC performed the low level control was not acceptable in February 2019. In the South 200 Hall glucometer #1 had 21 out of 21 (3/1=23, 3/4=20, 3/5=22, 3/6=24, 3/7=21, 3/8=26, 3/11=20, 3/12=23, 3/13=21, 3/14=22, 3/15=20, 3/18=24, 3/19=20, 3/20=19, 3/21=21, 3/22=20, 3/23=20, 3/25=22, 3/26=20, 3/27=19, and 3/28=20) days and #2 had 13 out of 13 (3/1=20, 3/4=24, 3/5=22, 3/6=21, 3/18=23, 3/19=20, 3/20=24, 3/21=22, 3/22=20, 3/25=20, 3/26=19, 3/27=22, and 3/28=20) days QC performed the low level control was not acceptable in March 2019. In the South 200 Hall glucometer #1 had 2 out of 2 (4/1=20 and 4/2=19) days QC

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