

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2063581	(X3) Date Survey Completed 11/08/2019
Name of Provider or Supplier Ten Broeck Tampa Inc	Street Address, City, State 29910 State Road 56, Wesley Chapel, 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	A complaint survey for complaint number 2019017321, was conducted on 11/06/19 to 11/08/19 at Ten Broeck Tampa DBA North Tampa Behavioral Health. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 2:15 PM on 11/08/19. The laboratory failed to follow manufacturers' instructions while running waived tests (Glucose, Urine dipstick, Urine Pregnancy, and Urine drug test cup). (See D1001 and D8201). The following Condition was not met: D8100 - 42 C.F.R. 493.1771 Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.
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 interviews with the Laboratory Director, Director of Quality & Compliance, Director of Risk Management, Admissions Counselor, and the Admissions Specialist, the certificate of waiver laboratory failed to follow manufacturers' instructions (MI) for 4 out of 4 waived tests: urine dipstick testing (Medline Urinalysis Reagent Strips), urine drug testing (UScreen Drug Test Cup), urine pregnancy testing (Medline hCG Pregnancy Test Strip), and blood glucose testing (EVENCARE G2 Blood Glucose Monitoring System, EVENCARE G2 Glucose Control Solutions, and EVENCARE G2 blood glucose test strips) for an undetermined amount of time. Findings Included: A tour on 11/06/19 at 10:30 AM of the testing areas where waived testing was performed revealed 5 different areas: Admitting, Unit A, Unit B, Unit C, and Unit M. The Units were part of the residential living areas. All waived testing to include urine dipstick testing (Medline Urinalysis</p>

Reagent Strips), urine drug testing (UScreen Drug Test Cup), urine pregnancy testing (Medline hCG Pregnancy Test Strip), and blood glucose testing (EVENCARE G2 Blood Glucose Monitoring System, EVENCARE G2 Glucose Control Solutions and EVENCARE G2 blood glucose test strips) was observed to be performed in the Admitting area. At 11:00 AM on 11/06/19, in the Admitting area, expired glucometer controls (expired 09/04/19) were observed in the drawer where the glucometer and test strips were stored. The controls were noted to be opened on 08/16/11. Photographic evidence was obtained. There were no logs of quality control (QC), temperature, or humidity present for review. The MI for the EVENCARE G2 Glucose Control Solutions stated, "Control solution should be stored at 59-86 degrees Fahrenheit. Do not use if the expiration date has passed. Discard any unused control solution 90 days after first opening or after expiration date." The MI for the EVENCARE G2 blood glucose test strips revealed the following QC information: "Run Low and High controls solution tests ...Do control tests: If your test results do not agree with how you feel. At least once per week to make sure the meter and test strips are working properly. If your test strips were stored at temperatures and humidity outside proper storage conditions. When you use your meter for the first time. Every time you open a new bottle of test strips. To practice your testing technique. If you drop your meter." The MI for the EVENCARE G2 Blood Glucose Monitoring System (glucometer) revealed that the intended use of the monitoring system was for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The meter has an operating temperature of 50-104 degrees Fahrenheit and less than 85% humidity. At 11:00 AM on 11/06/19, an Admission Counselor was observed running a urine drug screening, a urine dipstick test, and a urine pregnancy test in the Admitting area. No timer was observed in use. The Admission's Counselor was asked how long the test was required to be ran. The Admission Counselor stated that the tests only took a few seconds before the results could be read. Review of the MI for the UScreen Drug Test Cup revealed this was a rapid, screening test for the qualitative detection of multiple drugs in human urine at specified cut off levels. The test should be stored at 39-86 degrees Fahrenheit in the sealed pouch. When performing the test, "Wait 5 minutes to determine a positive result. Do not read results after 5 minutes. Results after more than 5 minutes may be not accurate and should not be read." The MI for the Medline Urinalysis Reagent Strips (urine dipstick test) revealed the intended use was for the qualitative and semi-quantitative detection of several analytes in urine. The reagent strips (dipsticks) should be stored at 36-86 degrees Fahrenheit. It also stated that, "Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter. The sensitivities are based on visual read studies." A review of the table revealed the read time for Glucose and Bilirubin was 30 seconds, Ketone was 40 seconds, Specific Gravity was 45 seconds, Blood, pH, Protein, Urobilinogen, and Nitrite was 60 seconds, and Leukocytes was 120 seconds. The MI also stated under QC "For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls in the following conditions." The conditions included when opening a new bottle, testing the strips monthly that were stored for more than 30 days, to ensure reagent storage integrity, to train new testing people, to confirm test performance, and when patients symptoms and conditions do not match the results obtained. The MI for the Medline hCG (human chorionic gonadotropin) Pregnancy Test Strip (urine pregnancy test) revealed the intended use was for the qualitative detection of hCG in urine to aid in the early detection of pregnancy. The test should be stored at 36-86 degrees Fahrenheit. The directions for use stated, " ...immerse the test strip vertically in the urine specimen for at least 5 seconds...Place the test strip on a non-absorbent, flat

surface, start the timer and wait for the red line(s) to appear. Read the result at 3-4 minutes. Do not interpret the results after the appropriate read time. It is important that the background is clear before the result is read." Interview on 11/06/19 at 11:30 AM with the Admissions Specialist confirmed that no quality control, room temperature, or humidity logs were being done or recorded. During the tour conducted on 11/06/19 at 10:30 AM, the 4 residential units were observed to only perform glucose testing. There was no humidity documented where the glucometer was stored. This was confirmed by the Laboratory Director on 11/08/19 at 1:00 PM. The MI for the EVENCARE G2 Glucose Control Solutions stated 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 within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly." It also stated, "CAUTION: 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." Interview with the Director of Quality and Compliance on 11/07/19 at 11:00 AM revealed that the glucose QC should be run daily and if not within acceptable limits there should be a corrective action and the QC run again. She also stated that if not acceptable that glucometer should not be used to perform patient testing. She confirmed that there were no logs available for review prior to 06/01/19. This was confirmed during review of glucose QC logs by lack of documentation prior to 06/01/19. Review of QC logs from Unit A from 06/01/19 to 11/04/19 revealed no QC was performed on 11/03/19, 10/29/19, 10/28/19, 10/21/19, 09/23/19, 09/03/19, 09/02/19, 09/01/19, 08/31/19, 08/30/19, 08/29/19, 08/27/19, 08/19/19, 08/16/19, 08/12/19, 08/11/19, 08/07/19, 07/24/19, 07/15/19, 07/11/19, and 07/05/19. Continued review of the Unit A QC logs revealed QC was outside the acceptable range with no corrective action on the following days: (low acceptable range was 40-70) 10/24/19=21, 10/18/19=39, 10/17/19=39, 10/14/19=39, (low acceptable range was 39-69) 09/16/19=30, 09/15/19=30, 09/14/19=30, 09/13/19=29, 09/08/19=30, 09/07/19=32, 09/06/19=30, (low acceptable range was 41-71) 09/05/19=31, 08/26/19=37, (low acceptable range was 38-68) 07/25/19=36, 07/23/19=33, 07/22/19=36, (low acceptable range was 43-73) 07/13/19=34, 07/09/19=42, (high acceptable range was 162-219) 06/20/19=312, 06/19/19=301, and 06/07/19=236. Review of QC logs from Unit B from 06/01/19 to 11/04/19 revealed no QC was performed on 11/04/19, 10/22/19, 10/16/19, 10/11/19, 10/10/19, 10/08/19, 10/07/19, 10/06/19, 09/28/19, 09/19/19, 09/17/19, 09/08/19, 09/07/19, 09/03/19, 09/01/19, 08/27/19, 08/26/19, 08/25/19, 08/22/19, 08/12/19, 08/06/19, 08/03/19, 07/30/19, 07/28/19, 07/27/19, 07/25/19, 07/24/19, 07/19/19, 07/15/19, 07/11/19, 07/09/19, 07/08/19, 07/07/19, 07/06/19, 07/02/19, 06/28/19, 06/19/19, 06/15/19, 06/14/19, 06/10/19, 06/09/19, 06/08/19, 06/07/19, 06/06/19, 06/05/19, 06/04/19, 06/03/19, 06/02/19, and 06/01/19. Continued review of the Unit B QC logs revealed QC was outside the acceptable range with no corrective action on the following days: (low acceptable range 40-70) 10/26/19=94, (low acceptable range 41-71) 09/14/19=78, 09/06/19=37, 09/05/19=38, 09/04/19=40, 08/29/19=33, 08/28/19=38, 08/13/19=40, 08/10/19=40, 08/09/19=40, 08/07/19=39, 08/04/19=40, (low acceptable range 38-68) 07/20/19=34, (high acceptable range 162-219) 08/05/19=220, 07/05/19=306, 07/04/19=304, 07/01/19=245, and 06/30/19=302. Review of QC logs from Unit C from 06/01/19 to 11/04/19 revealed no QC was performed on 11/04/19, 11/03/19, 11/02/19, 11/01/19, 10/27/19, 10/24/19, 10/23/19, 10/22/19, 10/21/19, 10/20/19, 10/19/19, 10/18/19, 10/17/19, 10/16/19, 10/15/19, 10/14/19, 10/13/19, 10/12/19, 10/11/19, 10/09/19, 10/08/19, 10/07/19, 10/06/19, 10/05/19, 10/04/19, 10/03/19, 10/02/19, 10/01/19, 09/30/19, 09/29/19, 09/28/19, 09/27/19, 09/26/19, 09/25/19, 09/24/19, 09/23/19, 09/22/19, 09/21/19, 09/20/19, 09/19/19, 09/18/19, 09/17/19, 09/16/19, 09/15/19, 09/14/19, 09/13/19, 09/12/19, 09/11/19, 09/10/19,

09/08/19, 09/07/19, 09/06/19, 09/05/19, 09/04/19, 09/03/19, 09/02/19, 09/01/19, 08/31/19, 08/30/19, 08/29/19, 08/24/19, 08/23/19, 08/20/19, 08/17/19, 08/13/19, 08/07/19, 08/06/19, 08/05/19, 08/03/19, 07/30/19, 07/11/19, 07/09/19, 07/08/19, 06/28/19, 06/10/19, 06/09/19, 06/08/19, 06/07/19, 06/06/19, 06/05/19, 06/04/19, 06/03/19, 06/02/19, and 06/01/19. The following days the QC on Unit C was outside the acceptable range with no corrective action taken: (low acceptable range 41-71) 08/28/19=23, 08/27/19=14, 08/26/19=22, (low acceptable range 38-68) 08/22/19=21, 08/21/19=26, 08/19/19=32, 07/05/19=28, 07/04/19=30, (low acceptable range 43-73) 08/18/19=41, 08/16/19=24, 08/15/19=20, 08/14/19=29, 08/11/19=40, 08/10/19=42, 08/09/19=31, 08/08/19=26, 08/04/19=34, 08/02/19=35, and (high acceptable range 164-222) 08/27/19=271. Review of QC logs from Unit M from 06/01/19 to 11/04/19 revealed no QC was performed on 10/15/19, 08/22/19, 08/18/19, 06/10/19, 06/09/19, 06/08/19, 06/07/19, 06/06/19, 06/05/19, 06/04/19, 06/03/19, 06/02/19, and 06/01/19. The following days the QC on Unit M was outside the acceptable range with no corrective action taken: (low acceptable range 40-70) 11/03/19=35, 11/02/19=39, 11/01/19=39, 10/29/19=37, 10/24/19=39, 10/23/19=38, (low acceptable range 39-69) 09/29/19=22, 09/28/19=27, 09/24/19=21, 09/23/19=28, 09/19/19=22, 09/18/19=26, 09/16/19=22, 09/15/19=30, 09/14/19=30, 09/11/19=32, 09/10/19=29, 09/09/19=37, 09/08/19=38, (low acceptable range 41-71) 09/03/19=27, 09/02/19=27, 09/01/19=29, 08/31/19=24. 08/30/19=30, 08/29/19=30, 08/28/19=34, 08/27/19=33, 08/26/19=31, 08/25/19=33, 08/24/19=30, 08/23/19=32, 08/21/19=31, 08/20/19=32, 08/19/19=32, 08/17/19=33, 08/16/19=32, 08/15/19=38, 08/13/19=34, 08/12/19=34, 08/11/19=34, 08/10/19=33, 08/09/19=35, 08/08/19=37, 08/07/19=34, 08/06/19=30, 08/05/19=34, 08/04/19=34, 08/03/19=35, 08/02/19=37, 08/01/19=34, 07/31/19=39, 07/30/19=40, 07/29/19=37, 07/28/19=36, 07/27/19=39, (low acceptable range 42-72) 06/21/19=39, 06/19/19=41, (high acceptable range 164-222) 09/26/19=241, 09/20/19=246, and 09/19/19=229. Review of policies and procedures to include the "Blood Glucose Monitoring" policy, most recently reviewed on 04/30/19, revealed no policy was in place for reviewing the glucose QC logs. Interview on 11/07/19 at 4:01 PM with the Laboratory Director confirmed that the glucose logs were not being reviewed. Review of the policy titled, "Waived Testing, with a revised and effective date of 09/23/13, and the policy titled "Blood Glucose Monitoring", most recently revised 05/18/16, revealed the policies for urine drug cup testing, urine pregnancy testing, and glucose did not follow manufacturers' instructions. Additionally, there was no policy for urine dipstick testing. Interview on 11/06/19 at 4:16 PM with the Director of Risk Management confirmed that the current policy for glucose testing was not reflective of what staff were doing and confirmed the policies for urine drug cup test, urine dipstick, and urine pregnancy did not describe procedures per MI requirements. Review of the the 96 Testing Personnel employee files revealed that 25 staff members had no training, 67 testing personnel did not have adequate training (only glucose and urine drug cup quiz), and 4 testing personnel had training. On 11/08/19 at 5:00 PM, the Director of Quality & Compliance confirmed that of the 96 employees on staff who perform waived lab testing 4 had training, 25 had no training, and 67 did not have adequate training. She also confirmed the Admission Counselor that was observed testing on 11/06/19 did not have training. Review of Quality Assurance records for 2019 revealed no mention of laboratory services. Interview on 11/08/19 at 2:00 PM with the Director of Risk Management confirmed that the Laboratory Services provided on-site or sent out were not part of their QAPI (Quality Assurance Performance Improvement). The Laboratory Director confirmed on 11/08/19 at 12:30 PM that patients' insulin is adjusted based on the glucose values provided by the glucometers. This was confirmed by the review of 10 patient charts (L1-L10) for insulin orders and glucometer readings.

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 interviews with the Laboratory Director, Director of Quality & Compliance, Director of Risk Management, Admissions Counselor, and the Admissions Specialist the laboratory failed to meet the requirement to follow manufacturers' instructions (MI) on 4 out of 4 waived tests (UScreen urine drug test cup, Medline Urine dipstick, Medline Urine Pregnancy, and Evencare G2 glucometer for glucose testing) 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.

This STANDARD is not met as evidenced by:

Based on observations, record review, and interviews with the Laboratory Director, Director of Quality & Compliance, Director of Risk Management, Admissions Counselor, and the Admissions Specialist the laboratory failed to perform waived testing in accordance with manufacturers' instructions (MI) on 4 out of 4 waived tests (UScreen urine drug test cup, Medline Urine dipstick, Medline Urine Pregnancy, and Evencare G2 glucometer for glucose testing) for an undetermined amount of time. Findings Included: A tour on 11/06/19 at 10:30 AM of the testing areas where waived testing was performed revealed 5 different areas. There was testing areas in admitting, and in each of the residential wings (Unit A, Unit B, Unit C, and Unit M). In the admitting area, all waived testing was observed to be performed to include: UScreen urine drug test cup, Medline Urine dipstick, Medline Urine Pregnancy, and Evencare G2 glucometer for glucose testing. Observation in the admitting area at 11:00 AM on 11/06/19 revealed expired glucometer controls (expired 09/04/19) in the drawer where the glucometer and test strips were stored. The controls were noted to be opened on 08/16/11. Photographic evidence was obtained. There were no logs of quality control (QC), temperature, or humidity present for review. The MI for the EVENCARE G2 Glucose Control Solutions stated, "Control solution should be stored at 59-86 degrees Fahrenheit. Do not use if the expiration date has passed. Discard any unused control solution 90 days after first opening or after expiration date." The MI for the EVENCARE G2 blood glucose test strips revealed the following QC information:

"Run Low and High controls solution tests ...Do control tests: If your test results do not agree with how you feel. At least once per week to make sure the meter and test strips are working properly. If your test strips were stored at temperatures and humidity outside proper storage conditions. When you use your meter for the first time. Every time you open a new bottle of test strips. To practice your testing technique. If you drop your meter." The MI for the EVENCARE G2 Blood Glucose Monitoring System (glucometer) revealed that the intended use of the monitoring system was for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The meter has an operating temperature of 50-104 degrees Fahrenheit and less than 85% humidity. At 11:00 AM on 11/06/19, an Admission Counselor was observed running a urine drug screening, a urine dipstick test, and a urine pregnancy test in the Admitting area. No timer was observed in use. The Admission's Counselor was asked how long the test was required to be ran. The Admission Counselor stated that the tests only took a few seconds before the results could be read. Review of the MI for the UScreen Drug Test Cup revealed this was a rapid, screening test for the qualitative detection of multiple drugs in human urine at specified cut off levels. The test should be stored at 39-86 degrees Fahrenheit in the sealed pouch. When performing the test, "Wait 5 minutes to determine a positive result. Do not read results after 5 minutes. Results after more than 5 minutes may be not accurate and should not be read." The MI for the Medline Urinalysis Reagent Strips (urine dipstick test) revealed the intended use was for the qualitative and semi-quantitative detection of several analytes in urine. The reagent strips (dipsticks) should be stored at 36-86 degrees Fahrenheit. It also stated that, "Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter. The sensitivities are based on visual read studies." A review of the table revealed the read time for Glucose and Bilirubin was 30 seconds, Ketone was 40 seconds, Specific Gravity was 45 seconds, Blood, pH, Protein, Urobilinogen, and Nitrite was 60 seconds, and Leukocytes was 120 seconds. The MI also stated under QC "For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls in the following conditions." The conditions included when opening a new bottle, testing the strips monthly that were stored for more than 30 days, to ensure reagent storage integrity, to train new testing people, to confirm test performance, and when patients symptoms and conditions do not match the results obtained. The MI for the Medline hCG (human chorionic gonadotropin) Pregnancy Test Strip (urine pregnancy test) revealed the intended use was for the qualitative detection of hCG in urine to aid in the early detection of pregnancy. The test should be stored at 36-86 degrees Fahrenheit. The directions for use stated, "...immerse the test strip vertically in the urine specimen for at least 5 seconds...Place the test strip on a non-absorbent, flat surface, start the timer and wait for the red line(s) to appear. Read the result at 3-4 minutes. Do not interpret the results after the appropriate read time. It is important that the background is clear before the result is read." Interview on 11/06/19 at 11:30 AM with the Admissions Specialist confirmed that no quality control, room temperature, or humidity logs were being done or recorded. During the tour conducted on 11/06/19 at 10:30 AM, the 4 residential units were observed to only perform glucose testing. There was no humidity documented where the glucometer was stored. This was confirmed by the Laboratory Director on 11/08/19 at 1:00 PM. The MI for the EVENCARE G2 Glucose Control Solutions stated 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 within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly." It also stated, "CAUTION: 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." Interview with the Director of Quality and Compliance on 11/07/19 at 11:00 AM revealed that the glucose QC should be run daily and if not within acceptable limits there should be a corrective action and the QC run again. She also stated that if not acceptable that glucometer should not be used to perform patient testing. She confirmed that there were no logs available for review prior to 06/01/19. This was confirmed during review of glucose QC logs by lack of documentation prior to 06/01/19. Review of QC logs from Unit A from 06/01/19 to 11/04/19 revealed no QC was performed on 11/03/19, 10/29/19, 10/28/19, 10/21/19, 09/23/19, 09/03/19, 09/02/19, 09/01/19, 08/31/19, 08/30/19, 08/29/19, 08/27/19, 08/19/19, 08/16/19, 08/12/19, 08/11/19, 08/07/19, 07/24/19, 07/15/19, 07/11/19, and 07/05/19. Continued review of the Unit A QC logs revealed QC was outside the acceptable range with no corrective action on the following days: (low acceptable range was 40-70) 10/24/19=21, 10/18/19=39, 10/17/19=39, 10/14/19=39, (low acceptable range was 39-69) 09/16/19=30, 09/15/19=30, 09/14/19=30, 09/13/19=29, 09/08/19=30, 09/07/19=32, 09/06/19=30, (low acceptable range was 41-71) 09/05/19=31, 08/26/19=37, (low acceptable range was 38-68) 07/25/19=36, 07/23/19=33, 07/22/19=36, (low acceptable range was 43-73) 07/13/19=34, 07/09/19=42, (high acceptable range was 162-219) 06/20/19=312, 06/19/19=301, and 06/07/19=236. Review of QC logs from Unit B from 06/01/19 to 11/04/19 revealed no QC was performed on 11/04/19, 10/22/19, 10/16/19, 10/11/19, 10/10/19, 10/08/19, 10/07/19, 10/06/19, 09/28/19, 09/19/19, 09/17/19, 09/08/19, 09/07/19, 09/03/19, 09/01/19, 08/27/19, 08/26/19, 08/25/19, 08/22/19, 08/12/19, 08/06/19, 08/03/19, 07/30/19, 07/28/19, 07/27/19, 07/25/19, 07/24/19, 07/19/19, 07/15/19, 07/11/19, 07/09/19, 07/08/19, 07/07/19, 07/06/19, 07/02/19, 06/28/19, 06/19/19, 06/15/19, 06/14/19, 06/10/19, 06/09/19, 06/08/19, 06/07/19, 06/06/19, 06/05/19, 06/04/19, 06/03/19, 06/02/19, and 06/01/19. Continued review of the Unit B QC logs revealed QC was outside the acceptable range with no corrective action on the following days: (low acceptable range 40-70) 10/26/19=94, (low acceptable range 41-71) 09/14/19=78, 09/06/19=37, 09/05/19=38, 09/04/19=40, 08/29/19=33, 08/28/19=38, 08/13/19=40, 08/10/19=40, 08/09/19=40, 08/07/19=39, 08/04/19=40, (low acceptable range 38-68) 07/20/19=34, (high acceptable range 162-219) 08/05/19=220, 07/05/19=306, 07/04/19=304, 07/01/19=245, and 06/30/19=302. Review of QC logs from Unit C from 06/01/19 to 11/04/19 revealed no QC was performed on 11/04/19, 11/03/19, 11/02/19, 11/01/19, 10/27/19, 10/24/19, 10/23/19, 10/22/19, 10/21/19, 10/20/19, 10/19/19, 10/18/19, 10/17/19, 10/16/19, 10/15/19, 10/14/19, 10/13/19, 10/12/19, 10/11/19, 10/09/19, 10/08/19, 10/07/19, 10/06/19, 10/05/19, 10/04/19, 10/03/19, 10/02/19, 10/01/19, 09/30/19, 09/29/19, 09/28/19, 09/27/19, 09/26/19, 09/25/19, 09/24/19, 09/23/19, 09/22/19, 09/21/19, 09/20/19, 09/19/19, 09/18/19, 09/17/19, 09/16/19, 09/15/19, 09/14/19, 09/13/19, 09/12/19, 09/11/19, 09/10/19, 09/08/19, 09/07/19, 09/06/19, 09/05/19, 09/04/19, 09/03/19, 09/02/19, 09/01/19, 08/31/19, 08/30/19, 08/29/19, 08/24/19, 08/23/19, 08/20/19, 08/17/19, 08/13/19, 08/07/19, 08/06/19, 08/05/19, 08/03/19, 07/30/19, 07/11/19, 07/09/19, 07/08/19, 06/28/19, 06/10/19, 06/09/19, 06/08/19, 06/07/19, 06/06/19, 06/05/19, 06/04/19, 06/03/19, 06/02/19, and 06/01/19. The following days the QC on Unit C was outside the acceptable range with no corrective action taken: (low acceptable range 41-71) 08/28/19=23, 08/27/19=14, 08/26/19=22, (low acceptable range 38-68) 08/22/19=21, 08/21/19=26, 08/19/19=32, 07/05/19=28, 07/04/19=30, (low acceptable range 43-73) 08/18/19=41, 08/16/19=24, 08/15/19=20, 08/14/19=29, 08/11/19=40, 08/10/19=42, 08/09/19=31, 08/08/19=26, 08/04/19=34, 08/02/19=35, and (high acceptable range 164-222) 08/27/19=271. Review of QC logs from Unit M from 06/01/19 to 11/04/19 revealed no QC was performed on 10/15/19, 08/22/19, 08/18/19, 06/10/19, 06/09/19, 06/08/19, 06/07/19, 06/06/19, 06/05/19, 06/04/19, 06/03/19, 06/02/19, and 06/01/19. The following

days the QC on Unit M was outside the acceptable range with no corrective action taken: (low acceptable range 40-70) 11/03/19=35, 11/02/19=39, 11/01/19=39, 10/29/19=37, 10/24/19=39, 10/23/19=38, (low acceptable range 39-69) 09/29/19=22, 09/28/19=27, 09/24/19=21, 09/23/19=28, 09/19/19=22, 09/18/19=26, 09/16/19=22, 09/15/19=30, 09/14/19=30, 09/11/19=32, 09/10/19=29, 09/09/19=37, 09/08/19=38, (low acceptable range 41-71) 09/03/19=27, 09/02/19=27, 09/01/19=29, 08/31/19=24, 08/30/19=30, 08/29/19=30, 08/28/19=34, 08/27/19=33, 08/26/19=31, 08/25/19=33, 08/24/19=30, 08/23/19=32, 08/21/19=31, 08/20/19=32, 08/19/19=32, 08/17/19=33, 08/16/19=32, 08/15/19=38, 08/13/19=34, 08/12/19=34, 08/11/19=34, 08/10/19=33, 08/09/19=35, 08/08/19=37, 08/07/19=34, 08/06/19=30, 08/05/19=34, 08/04/19=34, 08/03/19=35, 08/02/19=37, 08/01/19=34, 07/31/19=39, 07/30/19=40, 07/29/19=37, 07/28/19=36, 07/27/19=39, (low acceptable range 42-72) 06/21/19=39, 06/19/19=41, (high acceptable range 164-222) 09/26/19=241, 09/20/19=246, and 09/19/19=229. Review of policies and procedures to include the "Blood Glucose Monitoring" policy, most recently reviewed on 04/30/19, revealed no policy was in place for reviewing the glucose QC logs. Interview on 11/07/19 at 4:01 PM with the Laboratory Director confirmed that the glucose logs were not being reviewed. Review of the policy titled, "Waived Testing, with a revised and effective date of 09/23/13, and the policy titled "Blood Glucose Monitoring", most recently revised 05/18/16, revealed the policies for urine drug cup testing, urine pregnancy testing, and glucose did not follow manufacturers' instructions. Additionally, there was no policy for urine dipstick testing. Interview on 11/06/19 at 4:16 PM with the Director of Risk Management confirmed that the current policy for glucose testing was not reflective of what staff were doing and confirmed the policies for urine drug cup test, urine dipstick, and urine pregnancy did not describe procedures per MI requirements. Review of the the 96 Testing Personnel employee files revealed that 25 staff members had no training, 67 testing personnel did not have adequate training (only glucose and urine drug cup quiz), and 4 testing personnel had training. On 11/08/19 at 5:00 PM, the Director of Quality & Compliance confirmed that of the 96 employees on staff who perform waived lab testing 4 had training, 25 had no training, and 67 did not have adequate training. She also confirmed the Admission Counselor that was observed testing on 11/06/19 did not have training. Review of Quality Assurance records for 2019 revealed no mention of laboratory services. Interview on 11/08/19 at 2:00 PM with the Director of Risk Management confirmed that the Laboratory Services provided on-site or sent out were not part of their QAPI (Quality Assurance Performance Improvement). The Laboratory Director confirmed on 11/08/19 at 12:30 PM that patients' insulin is adjusted based on the glucose values provided by the glucometers. This was confirmed by the review of 10 patient charts (L1-L10) for insulin orders and glucometer readings.