

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2024541	(X3) Date Survey Completed 12/07/2018
Name of Provider or Supplier Center For Sight Pl	Street Address, City, State 1370 East Venice Ave Suite 205, Venice, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observations and interview with the Director of Operations, the laboratory failed to ensure the Chlorazol Black E was not expired prior to patient testing since September 15, 2018. Findings Included: A tour of the laboratory on 12/07/2018 at 10:00 a.m. revealed a bottle of Chlorazol Black E (Lot #6259) which had an expiration date of 09/15/2018. There were 2 more bottles of Chlorazol Black E (Lot#6259) with the expiration date of 09/15/2018 found in examination rooms. During an interview on 12/07/2018 at 10:00 AM, the Director of Operations confirmed that the Chlorazol Black E was expired and had been used for patient testing. The laboratory had ordered a new lot of Chlorazol Black E on 09/10/2018 but had not replaced the expired Chlorazol Black E with the new reagent.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the</p>

laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the facility failed to document corrective action when the humidity was out of range for 2 out of 2 years reviewed (2017 - 2018). Findings included: 1. Record review of the "Cryostat Maintenance" logs revealed that the acceptable range for humidity was missing from the log. The instrument manual stated the maximum humidity should be 60%. The following dates had degrees of humidity out of range with no corrective action documented: 1. 01/04/2017: documented humidity of "68" 2. 01/11/2017: documented humidity of "64" 3. 01/18/2017: documented degrees of "64" 4. 01/25/2017: documented degrees of "64" 5. 02/01/2017: documented degrees of "62" 6. 02/08/2017: documented degrees of "68" 7. 02/15/2017: documented degrees of "62" 8. 02/22/2017: documented degrees of "68" 9. 03/01/2017: documented degrees of "62" 10. 03/08/2017: documented degrees of "68" 11. 03/15/2017: documented degrees of "62" 12. 03/22/2017: documented degrees of "68" 13. 03/29/2017: documented degrees of "64" 14. 04/05/2017: documented degrees of "64" 15. 05/03/2017: documented degrees of "62" 16. 05/17/2017: documented degrees of "64" 17. 05/19/2017: documented degrees of "62" 18. 05/31/2017: documented degrees of "62" 19. 06/07/2017: documented degrees of "62" 20. 06/09/2017: documented degrees of "62" 21. 06/21/2017: documented degrees of "62" 22. 06/28/2017: documented degrees of "64" 23. 07/05/2017: documented degrees of "66" 24. 07/12/2017: documented degrees of "64" 25. 07/19/2017: documented degrees of "64" 26. 08/02/2017: documented degrees of "65" 27. 08/09/2017: documented degrees of "62" 28. 08/16/2017: documented degrees of "64" 29. 08/23/2017: documented degrees of "62" 30. 08/30/2017: documented degrees of "64" 31. 09/06/2017: documented degrees of "64" 32. 09/13/2017: documented degrees of "64" 33. 09/15/2017: documented degrees of "66" 34. 09/27/2017: documented degrees of "62" 35. 10/04/2017: documented degrees of "62" 36. 10/11/2017: documented degrees of "66" 37. 10/18/2017: documented degrees of "69" 38. 11/08/2017: documented degrees of "61" 39. 11/22/2017: documented degrees of "69" 40. 11/29/2017: documented degrees of "64" 41. 12/13/2017: documented degrees of "69" 42. 12/20/2017: documented degrees of "64" 43. 12/27/2017: documented degrees of "62" 44. 01/10/2018: documented degrees of "62" 45. 01/24/2018: documented degrees of "61" 46. 02/07/2018; documented degrees of "62" 47. 02/09/2018: documented degrees of "66" 48. 02/28/2018: documented degrees of "62" 49. 03/21/2018: documented degrees of "64" 50. 05/09/2018: documented degrees of "62" 51. 05/16/2018: documented degrees of "64" 52. 05/23/2018: documented degrees of "64" 53. 05/30/2018: documented degrees of "64" 54. 06/06/2018: documented degrees of "64" 55. 06/13/2018: documented degrees of "68" 56. 06/20/2018: documented degrees of "62" 57. 06/27/2018: documented degrees of "64" 58. 07/11/2018: documented degrees of "62" 59. 07/18/2018: documented degrees of "62" 60. 08/01/2018: documented degrees of "64" 61. 08/08/2018: documented degrees of "62" 62. 08/10/2018: documented degrees of "64" 63. 08/15/2018: documented degrees of "62" 64. 08/27/2018: documented degrees of "64" 65. 08/29/2018: documented degrees of "68" 66. 09/05/2018: documented degrees of "68" 67. 09/12/2018: documented degrees of "64" 68. 09/26/2018: documented degrees of "62" 69. 10/03/2018: documented degrees of "62" 70. 10/17/2018: documented degrees of "62" 71. 10/24/2018: documented degrees of "90" 72. 11/07/2018: documented degrees of "68" 73. 11/13/2018: documented degrees of "64" 74. 11/14/2018: documented degrees of "66" 75. 11/21/2018: documented degrees of "68" 76. 11/28/2018: documented degrees of "68" 77. 12/04/2018: documented degrees of "64" 2. In an interview on 12/07/2018 at 11:15 AM, the Director of Operations confirmed that no corrective action was

documented for the out of range humidity for 2 out of 2 years. The laboratory had tried a de-humidifier but temperature of cryostat rose. Then the laboratory tried to lower room temperature but the patient exam room is on the same thermostat and patients complained the exam room was too cold. So, the laboratory decided to accept degrees of humidity greater than 60.