

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1079153	<b>(X3) Date Survey Completed</b>  03/26/2025
<b>Name of Provider or Supplier</b>  Oswego Immediate Care	<b>Street Address, City, State</b>  6701 Us Highway 34, Oswego, IL	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> 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 laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's package inserts, laboratory records, lack of documentation, and interview with technical consultant (TC) #3, the laboratory failed to perform corrective actions for out of range humidity readings for 173 of 378 dates reviewed, affecting patient testing in the specialties of chemistry and hematology from March 2024 through the date of survey, 03/26/2025. Findings include: 1. Upon a tour of the laboratory on 03/26/2025, at 08:27 am, surveyors observed routine chemistry testing performed on the Abbott i-Stat analyzer (Serial Number: (21)326600) and hematology testing performed on the Sysmex XP-300 (Serial Number: A8051) and the Alere Triage Meter Pro (Serial Number: 00079816 WW). 2. Review of manufacturer's package inserts revealed the following environmental requirements for humidity: a) Abbott i-Stat: Under "Specifications", on page "3-2", "Relative Humidity   10-90% non-condensing". b) Sysmex XP-300: Under "1.8.1 Environmental Requirements", on page "1-19", "(2) Relative Humidity: 30 - 85%". c) Alere Triage Meter Pro: Under "Appendix A Specifications", on page 76, "Humidity   10% - 85%". 3. Review of laboratory records revealed the log titled, "Temperature and Humidity Logbook", which indicated the acceptable range of</p>

humidity to be "30 to 70%". 4. Review of laboratory records revealed 173 of 378 dates reviewed from March 2024 through the date of survey, 03/26/2025, were below the minimum level of 30% humidity for acceptable analyzer performance with no corrective action documented. Date: Humidity: 03/15/2024 28% 03/16/2024 27% 03/17/2024 21% 03/18/2024 14% 03/19/2024 14% 03/20/2024 16% 03/21/2024 12% 03/22/2024 12% 03/23/2024 19% 03/24/2024 13% 03/25/2024 16% 03/27/2024 22% 03/28/2024 19% 03/29/2024 19% 03/31/2024 28% 04/03/2024 27% 04/04/2024 26% 04/05/2024 25% 04/06/2024 21% 04/07/2024 23% 04/10/2024 29% 04/11/2024 28% 04/13/2024 27% 04/16/2024 26% 04/19/2024 29% 04/20/2024 22% 04/21/2024 19% 04/22/2024 21% 04/23/2024 23% 04/24/2024 26% 04/25/2024 22% 04/26/2024 23% 08/06/2024 29% 10/02/2024 28% 10/03/2024 29% 10/08/2024 28% 10/15/2024 28% 10/16/2024 23% 10/17/2024 22% 10/18/2024 22% 10/19/2024 25% 10/20/2024 27% 10/21/2024 27% 10/22/2024 27% 10/24/2024 26% 10/27/2024 24% 10/28/2024 23% 11/01/2024 27% 11/02/2024 26% 11/03/2024 26% 11/08/2024 28% 11/09/2024 29% 11/12/2024 27% 11/13/2024 25% 11/21/2024 22% 11/22/2024 28% 11/23/2024 26% 11/24/2024 26% 11/26/2024 21% 11/27/2024 20% 11/28/2024 18% 11/29/2024 12% 11/30/2024 6% 12/01/2024 19% 12/02/2024 4% 12/03/2024 4% 12/04/2024 10% 12/05/2024 1% 12/06/2024 1% 12/07/2024 4% 12/08/2024 17% 12/09/2024 27% 12/10/2024 19% 12/11/2024 15% 12/12/2024 1% 12/13/2024 1% 12/14/2024 4% 12/15/2024 25% 12/17/2024 22% 12/18/2024 15% 12/19/2024 17% 12/20/2024 20% 12/21/2024 11% 12/22/2024 15% 12/23/2024 20% 12/24/2024 21% 12/25/2024 18% 12/26/2024 25% 12/30/2024 26% 12/31/2024 28% 01/01/2025 21% 01/02/2025 15% 01/03/2025 13% 01/04/2025 6% 01/05/2025 4% 01/06/2025 7% 01/07/2025 4% 01/08/2025 6% 01/09/2025 0% 01/10/2025 10% 01/11/2025 12% 01/12/2025 13% 01/13/2025 6% 01/14/2025 4% 01/15/2025 0% 01/16/2025 4% 01/17/2025 11% 01/18/2025 15% 01/19/2025 -% 01/20/2025 0% 01/21/2025 0% 01/22/2025 0% 01/23/2025 1% 01/24/2025 0% 01/25/2025 0% 01/26/2025 0% 01/27/2025 0% 01/28/2025 1% 01/29/2025 10% 01/30/2025 8% 01/31/2025 25% 02/01/2025 17% 02/02/2025 17% 02/03/2025 23% 02/04/2025 16% 02/05/2025 11% 02/06/2025 16% 02/07/2025 8% 02/08/2025 7% 02/09/2025 11% 02/10/2025 1% 02/11/2025 6% 02/12/2025 4% 02/13/2025 6% 02/14/2025 0% 02/15/2025 8% 02/16/2025 10% 02/17/2025 0% 02/18/2025 0% 02/19/2025 0% 02/20/2025 0% 02/21/2025 0% 02/22/2025 0% 02/23/2025 0% 02/24/2025 13% 02/25/2025 21% 02/26/2025 21% 02/27/2025 22% 02/28/2025 18% 03/01/2025 24% 03/02/2025 22% 03/03/2025 21% 03/04/2025 26% 03/05/2025 25% 03/06/2025 19% 03/07/2025 17% 03/08/2025 18% 03/09/2025 17% 03/10/2025 19% 03/11/2025 21% 03/12/2025 14% 03/13/2025 16% 03/16/2025 26% 03/17/2025 18% 03/18/2025 22% 03/19/2025 28% 03/20/2025 25% 03/21/2025 18% 03/22/2025 18% 03/23/2025 16% 03/24/2025 19% 03/25/2025 16% 03/26/2025 17% 5. Interview with TC #3 on 03/26/2025, at 12:30 pm, confirmed the laboratory failed to perform corrective actions for out of range humidity readings for 173 of 378 dates reviewed.