

*Date: October 29, 2015*

# **LABORATORY ALERT**

*Subject: Temperature Plan of Action*

*The Laboratory is informing you of the following action plan:*

<b>Issue:</b>	With the temperature being out of range we must ensure the quality and safety of patient results. To ensure the quality of our patient results we will implement the following actions listed below.
<b>Effective date:</b>	<b>October 28, 2015</b>
<b>Temperature Plan of Action</b>	<ol style="list-style-type: none"> <li>1. All manufacturers will be contacted by the supervisor to assess the effect of elevated temperatures on their products. Documentation will be kept with all corrective action for this incident.</li> <li>2. External QC will be run as follows: <ul style="list-style-type: none"> <li>• Strep A, Influenza, RSV, HIV, HCG and TCA kits once a day at mid-day.</li> <li>• Verify Now instrument, PH meter, Osmo, FFN meter, and Occult Blood with every patient that is tested.</li> </ul> </li> <li>3. In the event that an instrument shuts down due to temperature issues, call for service and get a reference number. Send the samples that cannot be tested to Shady Grove.</li> <li>4. Room Temperature will be recorded every hour starting on 10/28/15, at 12:00 PM, until the temperature is maintained in range over consecutive days.</li> <li>5. If the room temperature exceeds 30°C, the TIC will notify the supervisor, and will attach the English Text Code to any results from the Strep A, Influenza, RSV, and TCA tests.</li> <li>6. As long as the temperature is above 25°C (temperature limit for Verify Now reagent), the English Text Code in reference to temperature will be attached to all Verify Now results.</li> <li>7. If the temperature is above 27° C (temperature limit for OraSure HIV Kit), the sample will be sent to Shady Grove.</li> <li>8. The supervisor will document the date range which exceeded temperature limits on a QV form including appropriate corrective action.</li> </ol> <p>English Text code <b>RTEMP</b> =  “Reagent storage temperature exceeded manufacturer’s specified range, additional QC performed and within range”</p>
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<b>ZMorrow/10.28.2015</b>	