TEMPERATURE EXCURSION INCIDENT REPORT

NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE
BUREAU OF IMMUNIZATION ● COVID-19 VACCINATION PROGRAM
347-396-2404 (Phone) ● 347-396-8841 (Fax) ● PQAUnit@health.nyc.gov

In the event of a temperature excursion, contact the vaccine manufacturers, complete and submit this form to the New York City Department of Health and Mental Hygiene, Bureau of Immunization, Provider Quality Assurance Unit. This report serves as a record of the incident, the steps taken to determine vaccine viability, and the disposition of the affected vaccines. Keep this report for your records.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Contact Info</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>1-866-663-3762</td>
<td>Sars-COV-2 (Moderna)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.modernatx.com">www.modernatx.com</a></td>
<td></td>
</tr>
<tr>
<td>Pfizer</td>
<td>1-800-505-4426</td>
<td>Sars-COV-2 (Pfizer BioNtech)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.pfizer.com">www.pfizer.com</a></td>
<td></td>
</tr>
</tbody>
</table>

Facility Name: ___________________________ PIN #: ___________ Date Reported: ___________

Reported by (first & last name): ______________________ Phone #: ___________ Email: ______________________

Date of Excursion: ___________ Time of Excursion: ___________ Order ID (if applicable): __________

IMMEDIATE ACTION TAKEN

1. Were the Vaccine Coordinator or Back-up Vaccine Coordinator notified of the excursion?
   - YES □ NO □

2. What was the excursion temperature inside the affected storage unit(s) at the time the problem was discovered?
   - Refrigerator Temperature: _________°C or __________°F
   - Freezer Temperature: _________°C or __________°F
   - Ultra-Cold Freezer Temperature: _________°C or __________°F

3. How long were the vaccines exposed to inappropriate storage temperatures? Please record the total amount of time or cumulative time outside of range for each unit.
   - Refrigerator: _______ Days _______ Hours _______ Minutes
   - Freezer: _______ Days _______ Hours _______ Minutes
   - Ultra-Cold Freezer: _______ Days _______ Hours _______ Minutes

<table>
<thead>
<tr>
<th>Storage Type</th>
<th>Pfizer vaccine</th>
<th>Moderna vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezer Storage</td>
<td>Ultra-Cold (-60°C to -80°C)</td>
<td>to -20°C (up to 6 months in Freezer)</td>
</tr>
<tr>
<td></td>
<td>- up to 6 months in ultra-cold temperature freezer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- up to 15 days in thermal shipper with dry ice replenishment</td>
<td></td>
</tr>
<tr>
<td>Refrigerator Storage</td>
<td>2° to 8°C for up to 5 days</td>
<td>2° to 8°C for up to 30 days</td>
</tr>
<tr>
<td>Room temperature</td>
<td>Up to 6 hours</td>
<td>Up to 12 hours</td>
</tr>
<tr>
<td>Reconstitution required</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
4. What was the room temperature surrounding the affected unit at the time of the excursion? ________________

5. Were water bottles in the refrigerator at the time of the event?  □ YES  □ NO
   Were frozen coolant packs in the freezer at the time of the event?  □ YES  □ NO

6. Was an inventory of the vaccines within the affected storage unit conducted?  □ YES  □ NO

7. Vaccines in the affected storage unit quarantined within the unit and labeled “DO NOT USE” pending manufacturer’s input?  □ YES  □ NO
   *If your vaccine storage unit(s) cannot be reset to maintain the appropriate storage conditions, follow the EMERGENCY PLAN as described within the VFC Vaccine Management Plan.

8. Has the vaccine manufacturer been contacted for further guidance?  □ YES  □ NO

CAUSE OF EXCURSION:
☐ Power Outage Unit(s) not plugged in or not turned on
☐ Prolonged opening of refrigerator /freezer door
☐ Temperature Monitoring device moved/misplaced
☐ Unit’s temperature control knob setting is incorrect
☐ Poor air circulation inside and outside the unit(s)
☐ Operational problems with the storage unit(s)
☐ Other ________________________________

Type & Brand Name of Storage Unit Affected by Excursion:
☐ Small Stand-Alone Refrigerator  ☐ Pharmaceutical Grade (Stand-Alone Refrigerator)
☐ Small Stand-Alone Chest Freezer  ☐ Pharmaceutical Grade (Combined Refrigerator & Freezer)
☐ Stand-Alone Freezer  ☐ Small Household Refrigerator & Freezer (Refrigerator Only)
☐ Regular Stand-Alone Refrigerator  ☐ Regular Household Refrigerator & Freezer (Refrigerator Only)
☐ Regular Stand-Alone Chest Freezer  ☐ Large Household Refrigerator & Freezer (Refrigerator Only)
☐ Pharmaceutical Grade (Stand-Alone Freezer)  ☐ Pharmaceutical Grade (Ultra-Cold Freezer)

Storage Unit Brand Name: __________________________  Model/Serial #: _________________________
Thermometer Brand Name: __________________________ Model/Serial #: _________________________

COVID-19 Vaccines, Manufacturer & Lot Number(s) affected due to temperature excursion:

<table>
<thead>
<tr>
<th>Vaccine (Manufacturer)</th>
<th>Vaccine Type</th>
<th>Lot Number(s)</th>
<th>Lot Expiration Date</th>
<th>New Expiration Date (if applicable)</th>
<th>Number of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-COV-2® (Pfizer BioNtech)</td>
<td>COVID-19</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>SARS-COV-2® (Moderna)</td>
<td>COVID-19</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SARS-COV-2® (AstraZeneca)</td>
<td>COVID-19</td>
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Describe the incident and corrective actions taken:

__________________________________________________________________________________________________
__________________________________________________________________________________________________
__________________________________________________________________________________________________
__________________________________________________________________________________________________
__________________________________________________________________________________________________

BASED ON MANUFACTURER’S RESPONSE:

Quality of vaccines has not been compromised and may continue to be used. □ YES □ NO
[CONTINUE TO MANUFACTURER CASE NUMBER(S) SECTION /SIGN FORM ON PAGE 3]

Vaccines were not approved for further use and should be identified as “spoiled”. □ YES □ NO
[CONTINUE TO MANUFACTURER CASE NUMBER(S) SECTION /IDENTIFY ONLY SPOILED DOSES /SIGN FORM]

Manufacturer Case Number(s):

Moderna_________________________________ Pfizer______________________________

*PLEASE ATTACH COPIES OF ALL DOCUMENTS FROM THE MANUFACTURER STATING THE VIABILITY STATUS OF ALL VACCINES.
*DO NOT DISCARD VACCINES UNLESS DIRECTED BY THE MANUFACTURER(S).

NAME: ___________________________________ SIGNATURE: __________________________
DATE REPORTED: __________________________