AFFILIATED PHYSICIANS
ON-SITE VACCINATION AND WELLNESS SERVICES

P022 – On-Site Cold Chain Management

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Last Revised by: Shannon Dallas - DCPP

Purpose:

Establishing cold chain management processes with quality control measures is necessary for maintaining product quality and ensure compliance with global regulations and industry standards for the storage, handling and distribution of temperature-sensitive products. Affiliated Physicians takes this process extremely seriously, as diversion from following such protocols may lead to serious vaccine potency compromise or waste.

Key individuals who have direct management involvement in the Cold Chain process will be required to complete the CDC CCM training [training module(s) will be available to other individuals who choose to complete]. Vaccine Storage and Handling (cdc.gov)

Affiliated Physicians Call Tree for Afterhours

Designated Site Operations and AP IIT with overall responsibility for cold chain management 24/7

COLD CHAIN MANAGEMENT - Affiliated Physicians Call Tree for After-Hours

5p-9a and weekends

Designated Site Operations and IIT with overall responsibility for cold chain management 24/7

Field Site Director - Kevin Sonilal – 347.332.3971
Field Site Director - Robert Thomas – 516.708.5967
Regional Manager - Fernando Roldan – 973.207.9318
Regional Manager - Gio Andino – 939.308.1102
Regional Manager - Senora Hardy - 845.233.0128
Regional Manager - Will Riemer - 516.270.8078

Business Hours Process Owner

IIT - Miguel Rosario – 347.579.1841
IIT - Pedro Rosario – 914.580.9151
Senior Director of Operations - Annie Nelson – 516.343.8861

Executive Level communication channel for Cold Chain Management

Local cold chain coordinator – VP - Liz Morton – 203.273.3519
Executive VP - Stephen Heath – 845.233.1440

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Logistic Contacts

- VP - Liz Morton – (914) 999-6082
- Ops Lead - Michael Jazzo – (914) 730-2046
- Ops Manager - Nicole Crerand – (914) 570-3721
- Jennifer Gelormino – (914) 999-6084

Resources - for Emergency Cold Chain Management

Manufacturer [Janssen/Moderna/Pfizer]	Contact by person who is completing the temp excursion report. **For Manufacturer communication during natural disasters that may lead to vaccine temp excursions and risk vaccine viability at warehouse will be handled by Liz Morton and Ari Cukier. All other temperature excursions that occur at off-site vaccine clinics will be handled by each respective responder.**
Digital Data Logger - contact	SmartSense Customer Service – 1.866.806.2653 8a-5p or digisolutionsupport@digi.com for 24 hour support James T. – 269.945.9228
Utility Power Company	Con Edison – 1.800.752.6633 for 24/7 support
HOTLINE – Afterhours Process Owner	646.535.2318

Site Ops [clinical and non-clinical] New Hires who will be handling vaccine at vaccine clinics will require the following:

- Must have completed the CCM Policy Overview by Director(s)
- Must have completed the CCM – Storage and Handling training module certification and provide the certificate to compliance@affiliatedphysicians.com
- Must have received SmartSense Digi training – arranged between Site Ops and AP IIT [for Regional Managers and Directors ONLY]
- Must be confirmed by Director(s) that new hire is appropriately prepared for CCM management before being added to the Call Tree List and prior to working solo lead in the field. - Please send an email to compliance@affiliatedphysicians.com when new hire has completed the above.

Those who work in the field and those who are added to the Call Tree List must understand the strict responsibilities for Cold Chain Management – including when they will receive alerts, how to handle the alerts, communication required during the intervention and outcome phases for any warning zone temps or red alerts.

CCM Binders must be visible at each location where there is AP fridge for vaccine storage – Site Ops Process Owner is responsible for maintenance of and for updates. Binders include:

- CCM Policy
- Fridge QC Checklist
- Fridge Manual
- Daily On-Site Refrigerator and Vax Log
- Certificate of Calibration (CoC)

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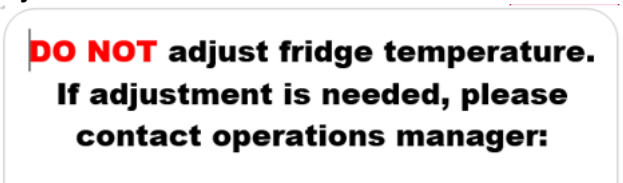
General CCM Checkpoints:

- ✓ Temp monitoring system (DDL – digital data loggers) must be in place and deemed operational at all vaccine clinic sites.
- ✓ Backup DDL is required for all sites storing vaccine.
- ✓ QC logger onsite must be maintained by Site Manager or Clinical Lead (CSM)
- ✓ Excursion Report must be readily available electronically to be completed for any temperature excursions outside of the ranges of 36-46 degrees F.
- ✓ Inactivated WarmMark backup supply must be available for potential vaccine transport.
- ✓ Shelves inside fridges must be labeled specific to Manufacturer and Beyond Use Date [BUD]
- ✓ Locks must be assessed and secure on fridge
- ✓ 2 sets of keys for fridge at all vaccine fridge locations
- ✓ Lockboxes for key storage must be onsite for all locations and secured to each fridge and/or nearby doorknob – codes set to same combination for all.
- ✓ **Sticker – DO NOT adjust fridge temp and contact Hotline or vaccine coordinator should adjustments be needed. – list name w Tel # on all fridges.**



- ✓ Sign must be visible near all outlets in use for AP fridges – indicating "Do Not Unplug".
- ✓ Site Operations Management - will train Site Management (SM) team and Regional Site Management.
- ✓ Director of Clinical Services will train TT / HOTLINE/CSM teams.
- ✓ IIT Lead responsible for training of the IIT team members and providing SmartSense digi login and training to new site ops hires.

****Important for Site Ops Management to review with the teams on the ground that the fridge is to remain closed at all times, unless getting vaccine out or counting. Even then, the fridge door should be closed immediately to avoid significant temperature changes****

Digital Data Loggers (DDL) – for fridge temp monitoring - how it works

- Setup
  - Initial setup – internal AP IT team will coordinate.
  - Once setup – parameters are set, warmup occurs, and monitoring takes place for 2-7 days.
  - Vaccine can be delivered and placed in fridge once a report shows steady temperatures between 38-44 degrees F. for consecutive 48 hours.
    - This report should be stored in the cloud for retrieval as needed by IT/Business Operations team
    - To show FRIDGE is ready for vaccine transport activation communication to compliance and logistics departments must take place by the IT/Business Operations team at the following three (3) stages:
      1. temperature probe placed in a new fridge
      2. when the temperatures reach within range
      3. when the temperatures have remained at a constant between 38-44 degrees F. for 48 hours

- DDL Offline - scheduled
  - Digi documentation required in Mcom for all scheduled OFFLINE activity and should include the following:
    - Anticipated date
    - Anticipated time
    - Vaccine management
  - Email notification by process owner to temperatureexcursion@affiliatedphysicians.com
  - Advance notification, if possible
  - Prior to placing vaccine back in fridge after offline period, temperature must show steady between 38.0 – 44.0 degrees F. for 12 hours.
- Certificate of Calibration (CoC)
  - AP internal IT team to confirm COC has been completed and readily available with each device initial setup.
  - Must maintain CoC copy in compliance Mcom board under CCM.
  - Complete every 2-3 years.
    - IT team will schedule COC accordingly with manufacturer every 2-3 years.
- Vaccine Storage and Use:

Pfizer's COVID vaccine:

12+ Purple Top - Once thawed, 1.8mL NS RECONSTITUTION must be completed before use

Non-diluted vaccine - viable for

- One (1) month in refrigerator at 36-46 degrees F., OR
- 2 hours at room temperature [47-77 degrees F.]
- Discard vaccine if not used within these time provisions.

Diluted Vaccine – viable for

- 6 hours at room temperature if diluted. Must discard after 6 hours. All vials need to be date and timed with dilution time.

12+ Gray Top - Once thawed, NO DILUTION required

- Can be at room temperature up to 12 hours before first puncture.
- Once punctured, must be used within 12 hours.
- Discard vaccine if not used within these time provisions.

5-11 Orange Top - Once thawed, 1.3mL NS RECONSTITUTION must be completed before use

- Can be at room temperature up to 12 hours before dilution
- Once diluted, must be used within 12 hours
- Discard vaccine if not used within this time frame

Moderna COVID vaccine:

- Once thawed, NO DILUTION required
- Can be stored at room temperature (47-77 degrees F.) up to 24 hours
- Vials must be discarded at 12 hours post first puncture if not used

Janssen (J&J) COVID vaccine:

- Once thawed, NO DILUTION required

- Can be stored at room temperature (47-77 degrees F.) up to 12 hours unpunctured
- Can be at room temperature (46-77 degrees F.) up to 2 hours after first puncture OR
- Can be stored at 36-46 degrees F. up to 6 hours after first puncture.
- Vials must be discarded after the allowable timeframes.

- Temperature Excursion
  - DDL monitoring is scheduled at a frequency of every 10 minutes.
  - Alerts will begin if temperature reaches outside of temp range of 37.0 – 45.0 degrees F.
  - Temperature Alerts Set -
    - Yellow - Alert – Warning Zone
      Requires monitoring and potential temperature adjustment(s)
      - Low end - reading of 36.0 - 36.9 degrees F.
      - High end - reading 45.1 – 46.0 degrees F.
    - Red Alert – High Threshold Emergency Zone
      Requires immediate action
      - Low end out-of-range reading 35.9 degrees F. or <
      - High end out-of-range reading 46.1 degrees F. or >

Alert Example:

Temperature Alert!
The 'Elmhurst Fridge-1 High' threshold has been violated.
Asset: Affiliated Physicians / Elmhurst / Elmhurst Fridge-1 (89624)
Sensor Point: Elmhurst Fridge-1
The current reading is 48.5 F
The threshold is set to 46.0 F
Alert occurred at 2/26/2021 10:59:50 AM (UTC-5)

Message Sent: 2/26/2021 10:59:57 AM (UTC-5)

- Temperature Alert Response – **during business hours**

Goal Optimal Range is 38.0 – 42.0 degrees F.
- No actions required.

Normal Range is 37.1 - 44.9 degrees F.
- Monitor and adjust as needed to return temp to **'Goal Optimal Range'**.

Warning Range [Yellow Alert] is 36.0 – 37.0 degrees F. & 45.0 – 46.0 degrees F.
- Alert email **from Digi** will auto-send a 'Warning Range' notification to designated Site Ops and internal IT.
  - Internal IT team must communicate with designated Site Operations team members to request confirmation the alert is being addressed.
    - Site Operations or IIT must communicate via Mcom and include the following:
      - **Acknowledge** the Alert
      - **Number** of vaccine vials involved
      - **Action**
      - Site operations responsible to provide additional update(s) via same Mcom thread with details of further action and subsequent resolution(s).

Red Zone is less than 36.0 degrees F., or greater than 46.0 degrees F.

- Hotline staff members will receive individual **alert emails and a temperature alert call**. Call will go directly to the Hotline telephone number for any **'Red Zone' alerts.**
- Digi full scale response with alert calls and emails to everyone on the temperature excursion email distribution list.
- Hotline will send an email alert to the temperature excursion distribution list.
- Hotline will reach out to contacts on the call tree, going in order, until there is a confirmed verbal response.
- Email designated Site Ops staff for 'Warning Range' temperature alerts.
- Call AP POC using the POC Call Tree.

- Temperature Alert Response – **after business hours** [nights, weekends, holidays]
  Goal Range is 38.0 – 42.0 degrees F.
  - No alerts - no contact or communication with site operations team necessary

  Normal Range is 37.1 - 44.9 degrees F.
  - Monitor phase by internal AP IT, no alerts and no contact or communication with site operations team necessary

Alert Process

The following process should be followed for all alerts

- Hotline staff members and designated CCM staff will receive an **alert email [for both 'Yellow' and 'Red' Zone alert] and a temperature alert call [for ONLY 'Red' Zone alerts]**.
- Mcom communication thread must be initiated by the process owner for any alert.
  - During business hours **AP IIT is the process owner** and must communicate with site operations staff.
  - After business hours **AP Hotline** is the process owner and must utilize the call tree list, going in order, until there is a confirmed verbal response.
- Designated Call Tree contact who receives the Hotline call must communicate via the same Mcom message thread by indicating the following:
  - **Acknowledge** the Alert
  - **Access** to location
  - **Number** of vaccine vials involved
  - **Action** taken
  - **Resolve:** Site operations must provide additional update(s) via Mcom thread with details of further action and subsequent resolution(s).

Temp Excursion Resolution

- For all RED ALERT temperature excursions outside of the 36-46 degrees F.
  - Mark vaccine as Do Not Use – DNU.
  - Call to manufacturer may be required.
  - Excursion report must be completed by SM and submitted to AP IIT and Compliance.
  - Compliance will investigate and communicate next steps and/or outcome via Mcom communication thread. This will include whether or not the vaccine is viable for use.
  - AP IIT must send supporting documentation for all temperature excursion investigations to applicable state or local health departments.

Additional Steps

- If Alert is within the 'warning' range must be acted upon immediately.

- If out-of-range, not self-correcting and after business hours, AP's point-of-contact must communicate with the site's point-of-contact for building access and coordinate temp excursion investigation.
- Staff member managing the excursion situation must remain in communication with temperature excursion team with status updates and remain on-site until resolution.
- CDC recommends - flashlights be on-site in event of power outage**. – encourage use of phone flashlight.**
- Refer to site specific building outlines and details located in SharePoint.
- Do not shut off – or acknowledge the excursion in Digi SmartSense website until resolution to the problem has been identified and properly addressed.

Clinic Vaccine Evacuation

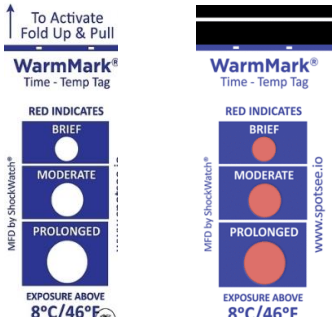
- Vaccine Evacuation may be required if fridge and/or backup cooler is not operational.
    - If there is no power outage, check with building maintenance to escalate and contact logistics for backup equipment.
- If vaccine must be evacuated from a non-functioning fridge, utilize the onsite operational backup cooler and report to HL.
    - Logistics must respond with plan for equipment exchange.
- If there are no other options, i.e. power outage, vaccine may need to be evacuated from on-site clinic to Pelham office. If this is required, Logistics must be notified immediately by telephone.

Cooler – Electric [backup system]

- Must be checked at start of each shift and confirm backup cooler is operational. Confirm the following:
    - Plugged in
    - Cooling properly
    - Temperature is within acceptable range between 38-44 degrees F.
    - After all safety checks completed and logged on the Fridge QC tracker, backup cooler is deemed ready and available for use as needed for temperature excursion alerts.

Vaccine Delivery –

- Vaccine courier must ask to speak to the Operations Site Manager or Clinical Site Manager (CSM).
- Must check fridge is operational before accepting delivery.
- Must review the WarmMark located in delivery to confirm temperature is within normal reading – all white circles.



    - Must know what a WarmMark temperature excursion looks like.

- If red dots are visible, temperature excursion has taken place and must be further assessed for vaccine viability. Call HL to report. Site Manager must communicate such findings with Regional Site Management.
- Site Manager must review the vaccine volume received by courier and document on the Fridge QC Log.
- Move older vaccine to 'OLDER' shelf and put the new vaccine on the 'NEW' shelf.
- If activating a WarmMark temp tag for vaccine transport, **Fold Up & Pull**. You will know that a WarmMark is activated when there is a black strip at the top.

Fridge QC Daily Logger

- By-month tracker must remain in designated location until last day of month. Must not be removed.
- Include the following:
  - Event Start Time
  - Confirm 2 sets of keys are present in the lockbox at start of shift (SOS)
  - Log fridge temp at SOS
  - Check cooler temp
  - Confirm vaccine vial count at SOS
  - Log any vaccine receivables during shift [immediately upon vaccine arrival to site]
  - Log any vaccine removed from fridge during shift
  - If vials remain at between 36-46 degrees F. during shift, okay to place non-used unpunctured vials back in fridge at end of shift.
  - Log vial count at end of shift (EOS)
  - Event End Time
  - Log fridge temperature at EOS
  - Confirm 2 sets of keys are present in the lockbox at EOS

QC Checks

The ***QC Checks*** are meant to keep all fridge/freezer sites organized and ascertain all sites are following the same procedures.

- All communication from Site Operations regarding deficiencies should include a plan of correction.

- ***Daily Fridge QC Checks*** must be completed by Site Management – as seen below

Refrigerator QC

Location:

Date	Event Start Time	Temp in Farenheit - Start	Vial count in fridge - Shift Start (include name of vaccine, lot #, and expiration date)	Recievables (include name of vaccine, lot #, and expiration date)	Vials removed from fridge	Vials count in fridge - Shift End	Event End Time	Temp in Farenheit - End	2 Sets of fridge keys accounted for (check + initial)	Site Manager Print	Site Manager Sign	Management Confirmed
5/1/21												

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Daily Fridge Vax Log – HC/ML

DAILY ON-SITE REFRIGERATOR AND VAX LOG

MUST BE PRINTED & COMPLETED ON A DAILY BASIS BY PM, HEAD CLINICIAN, & MANAGING LEAD

DATE:	SITE:	VACCINE:	PM:
LOT #:	LOT EXP:	DOSE 1:	HC:
LOT #:	LOT EXP:	DOSE 2:	ML:

CHECK OFF DOSE 1 OR 2

**LOG TOTAL # OF VIALS/DOSES (INCLUDING SAME DAY VACCINE DROP OFFS) FOR A TOTAL ON-SITE COUNT OF VAX INVENTORY)*	
LOG TEMPERATURE OF FRIDGE AT START OF EVENT 6:30AM (ON-SITE QC DOCUMENT RECORDS THE SAME TEMPERATURE)	
TOTAL # OF VIALS AT START OF EVENT:	TEMPERATURE OF FRIDGE AT START OF EVENT:
TOTAL # OF DOSES AT START OF EVENT:	FRIDGE TEMPERATURE MUST REMAIN WITHIN RANGE (36°-46°F)

PM, HC, AND ML TO LOG THE FOLLOWING INFORMATION EACH AND EVERY TIME VACCINES ARE REMOVED FROM FRIDGE

PM, HC & ML MONITOR & IMMEDIATELY ESCALATE ANY TEMPERATURE CHANGES/FLUCTUATIONS OUTSIDE OF RANGE (36°-46°F)

TIME:	DIAL READING:	NAME:	VIALS REMOVED:	TEMP OF FRIDGE:
TIME:	DIAL READING:	NAME:	VIALS REMOVED:	TEMP OF FRIDGE:
TIME:	DIAL READING:	NAME:	VIALS REMOVED:	TEMP OF FRIDGE:
TIME:	DIAL READING:	NAME:	VIALS REMOVED:	TEMP OF FRIDGE:
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TIME:	DIAL READING:	NAME:	VIALS REMOVED:	TEMP OF FRIDGE:
TIME:	DIAL READING:	NAME:	VIALS REMOVED:	TEMP OF FRIDGE:

TOTAL NUMBER OF VIALS AT END OF EVENT:	TEMPERATURE OF FRIDGE AT END OF EVENT:
TOTAL NUMBER OF DOSES AT END OF EVENT:	*FRIDGE TEMPERATURE MUST REMAIN WITHIN RANGE (36°-46°F)*

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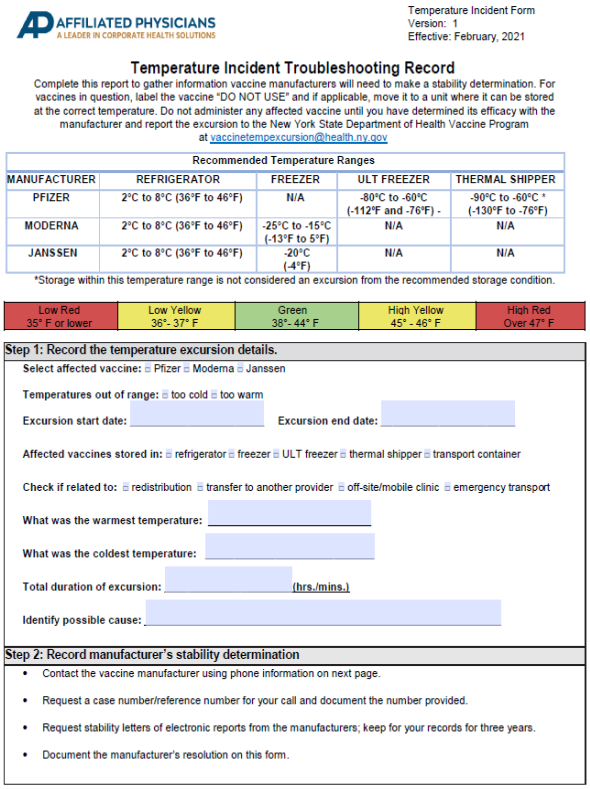
Temperature Excursion Report:



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Temperature Incident Form
Version: 1
Effective: February, 2021

Temperature Incident Troubleshooting Record

Complete this report to gather information vaccine manufacturers will need to make a stability determination. For vaccines in question, label the vaccine "DO NOT USE" and if applicable, move it to a unit where it can be stored at the correct temperature. Do not administer any affected vaccine until you have determined its efficacy with the manufacturer and report the excursion to the New York State Department of Health Vaccine Program at vaccinetempexcursion@health.ny.gov

Recommended Temperature Ranges

MANUFACTURER	REFRIGERATOR	FREEZER	ULT FREEZER	THERMAL SHIPPER
PFIZER	2°C to 8°C (36°F to 46°F)	N/A	-80°C to -60°C (-112°F and -76°F) -	-90°C to -60°C * (-130°F to -76°F)
MODERNA	2°C to 8°C (36°F to 46°F)	-25°C to -15°C (-13°F to 5°F)	N/A	N/A
JANSSEN	2°C to 8°C (36°F to 46°F)	-20°C (-4°F)	N/A	N/A

*Storage within this temperature range is not considered an excursion from the recommended storage condition.

Low Red	Low Yellow	Green	High Yellow	High Red
35° F or lower	36°- 37° F	38°- 44° F	45° - 46° F	Over 47° F

Step 1: Record the temperature excursion details.

Select affected vaccine: ☐ Pfizer ☐ Moderna ☐ Janssen

Temperatures out of range: ☐ too cold ☐ too warm

Excursion start date: _____ Excursion end date: _____

Affected vaccines stored in: ☐ refrigerator ☐ freezer ☐ ULT freezer ☐ thermal shipper ☐ transport container

Check if related to: ☐ redistribution ☐ transfer to another provider ☐ off-site/mobile clinic ☐ emergency transport

What was the warmest temperature: _____

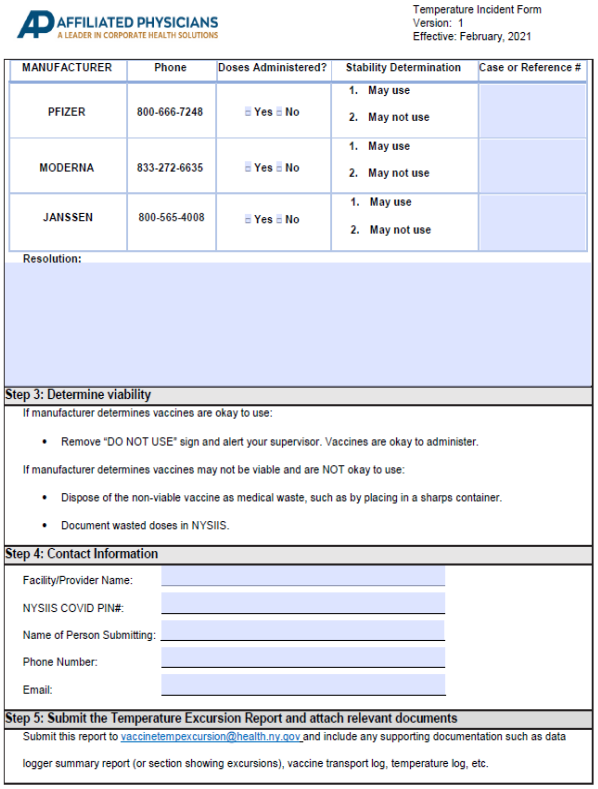
What was the coldest temperature: _____

Total duration of excursion: _____ (hrs./mins.)

Identify possible cause: _____

Step 2: Record manufacturer's stability determination

- Contact the vaccine manufacturer using phone information on next page.
- Request a case number/reference number for your call and document the number provided.
- Request stability letters of electronic reports from the manufacturers; keep for your records for three years.
- Document the manufacturer's resolution on this form.



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Temperature Incident Form
Version: 1
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MANUFACTURER	Phone	Doses Administered?	Stability Determination	Case or Reference #
PFIZER	800-666-7248	☐ Yes ☐ No	1. May use 2. May not use	
MODERNA	833-272-6635	☐ Yes ☐ No	1. May use 2. May not use	
JANSSEN	800-565-4008	☐ Yes ☐ No	1. May use 2. May not use	

Resolution:

Step 3: Determine viability

If manufacturer determines vaccines are okay to use:

- Remove "DO NOT USE" sign and alert your supervisor. Vaccines are okay to administer.

If manufacturer determines vaccines may not be viable and are NOT okay to use:

- Dispose of the non-viable vaccine as medical waste, such as by placing in a sharps container.
- Document wasted doses in NYSIIS.

Step 4: Contact Information

Facility/Provider Name: _____

NYSIIS COVID PIN#: _____

Name of Person Submitting: _____

Phone Number: _____

Email: _____

Step 5: Submit the Temperature Excursion Report and attach relevant documents

Submit this report to vaccinetempexcursion@health.ny.gov and include any supporting documentation such as data logger summary report (or section showing excursions), vaccine transport log, temperature log, etc.

1. For all temperature readings that go outside of 36-46 degrees F. for fridge or -13 to 5 degrees F. for freezer, a temperature excursion report must be completed.
2. Include the following when completing a **Temperature Excursion Report**:
    a. Manufacturer
    b. Site Location
    c. Temperature out-of-range
        i. Too warm
        ii. Too cold
    d. Excursion Start Date
    e. Excursion End Date
    f. Storage Unit type [fridge or freezer]
    g. Related to
    h. Warmest temperature during the excursion
    i. Coldest temperature during the excursion
    j. Total duration of the excursion prior to temperature stabilizing or need for vaccine evacuation
    k. Identify possible cause
    l. Include Lot # and expiration dates of vaccine located in storage unit
    m. Label vaccine 'Do Not Use' – and must remain under quarantine until further direction is provided by the Manufacturer.
    n. Contact Manufacturer
        i. Obtain guidance and submit via temperature excursion email.

1. Vaccine that is deemed viable can come out of quarantine
2. Vaccine that is deemed not viable, will remain in quarantine, will be transported by logistics back to main office and handled, according to regulations.

Re: Punctured or Non-punctured Vial Transfer from Clinic to Clinic

Okay to transport vaccine [punctured or non-punctured] from one community clinic to another – following best practices.

- May not be transported more than once onsite at a clinic, punctured or not punctured.
- Want to limit transferring from one clinic to another and use all vaccine at a single clinic whenever possible.
- If transporting COVID vaccine from one clinic to another, must be transported at a temperature of 36-46 degrees Fahrenheit via the following cooling mechanism:
    a. Foil pouch with ice pack or
    b. Hand held cooler with ice packs
        i. No WarmMark required for transport if vaccine vials have been warmed and held at room temperature prior to transport to alternate location.

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-Vaccine-Transport.pdf

https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-transportation-guidance.pdf

Best Practices:
Protect vaccine as much as possible from drops, shocks, and vibrations.
Minimize movement, transport vials in the carton whenever possible.
If individual vials must be transported:
Place vial(s) with padding material, i.e. bubble wrap or similar to prevent breaking.
Secure storage containers during transport.
Keep vaccine vials upright

Transporting vaccine to offsite clinics are allowed using strict storage and handling steps. Information within following link: transporting-covid19-vaccines-offsite.pdf (usp.org)

[i] Created Date – 03.10.21
[ii] Last reviewed/revised – 05.27.21, 03.10.22
[iii] Approved Date – 03.11.21