

Bivalent Pfizer and Moderna COVID-19 Booster Vaccine Update

Pediatric Release – October 2022

10/14/2022

Agenda

- Providing Access
- Packaging/Vial Description
- Initial Allocation and Ordering
- Special Considerations
- Bivalent Booster Order Form Walk-Through
- Q&A

Pediatric Moderna and Pfizer Vaccines

- FDA VRBPAC Committee met on October 12th to discuss data on Moderna and Pfizer Bivalent COVID-19 Vaccine Boosters. Following this meeting, the CDC approved EUAs for the 5 through 11 year old population
- **Initial Pfizer pediatric vaccine deliveries will begin the week of October 17th**
- Offering as many COVID-19 providers as possible with vaccine is critical to achieving equitable vaccine access during product roll out
- Even if ordering a small amount of vaccine, avoiding missed opportunities is critical during vaccine roll out

Pediatric Moderna and Pfizer Vaccine Eligibility

- 5-11 year olds at least two months since their primary series and/or last COVID-19 shot are projected to be eligible for Pfizer
- 6-11 year olds at least two months since their primary series and/or last COVID-19 shot are projected to be eligible for Moderna
- 12-17 year olds are also projected to be eligible for the Moderna bivalent booster with this EUA recommendation
- Mix and match is expected; children can receive either shot regardless of their primary series or previous boosters

Packaging/Diluent

- The packaging configuration for the Pfizer-BioNTech and the Moderna product will be 10-dose vials in cartons of 10 vials each (100 doses total). There will be a minimum 100 dose direct order quantity and a minimum 10 dose order quantity if ordering through M&D.
- Moderna orders that are less than 100 doses will not include ancillary supplies
- Once a vial is opened, doses must be used within 12 hours
- Both Pfizer and Moderna maintain the same storage conditions as each manufacturer's other COVID-19 vaccine products
 - Pfizer: 12 months ULT Freezer and/or 10 weeks for Refrigerator (check lot number lotexpiry.cvdvaccine.com)
 - Moderna: 6 months Freezer and/or 30 days Refrigerator (check lot number <https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup>)

Moderna COVID-19 Bivalent Vaccine Presentation

**DRAFT – SUBJECT TO
CHANGE PENDING
REGULATORY GUIDANCE
AND AUTHORIZATION/
APPROVAL – SHARED
FOR PLANNING
PURPOSES ONLY**









Bivalent Booster Dose Presentation

Age Group	6 years of age and older
Dose Volume	Bivalent Booster Doses 12 years of age and older: Each 0.5 mL 6 through 11 years of age: Each 0.25 mL
Dose Per Vial	12 years of age and older: 5 doses 6 through 11 years of age: 10 doses
Vial Cap Color	Dark Blue 
Vial Label	Gray Border NDC 80777-282-05 
Carton	Gray Border NDC 80777-282-99 

COVID-19, coronavirus disease 2019; EUA, Emergency Use Authorization; FDA, US Food and Drug Administration; US, United States. Moderna COVID-19 Vaccine Full EUA Prescribing Information.

Currently Available Dose Presentations - Moderna

PRE-EUA-Current as of 9/30/2022:
FOR PROVIDER TRAINING PURPOSES ONLY
DO NOT DISTRIBUTE

	Moderna COVID-19 Vaccine Primary Series (12 years of age and older)	Moderna COVID-19 Vaccine Primary Series* (6 through 11 years of age)	Moderna COVID-19 Vaccine Primary Series (6 months through 5 years of age)	Moderna COVID-19 Vaccine, Bivalent Booster Dose (6 years of age and older)
Dose Per Vial	Primary Series Doses only: maximum of 11 doses (range: 10-11 doses)	Primary Series Doses: 5 doses	Primary Series Doses: 10 doses	Bivalent Booster Dose for 12 years of age and older: 5 doses Bivalent Booster Dose for 6 through 11 years of age: 10 doses
Dose Volume	Primary Series Dose: Each 0.5 mL	Primary Series Dose: Each 0.5 mL	Primary Series Dose: Each 0.25 mL	Bivalent Booster Doses 12 years of age and older: Each 0.5 mL 6 through 11 years of age: Each 0.25 mL
Vial Label	 Blue border NDC 80777-273-10	 Purple border NDC 80777-275-05	 Magenta border NDC 80777-279-05	 Gray border NDC 80777-282-05
Carton	 Blue border NDC 80777-273-99	 Purple border NDC 80777-275-99	 Magenta border NDC 80777-279-99	 Gray border NDC 80777-282-99

Moderna Vials

PRE-EUA-Current as of 9/30/2022:
FOR PROVIDER TRAINING PURPOSES ONLY
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Storage and Handling

All Vial Presentations

Local Storage Options for Unpunctured Vials

(up to the Date of Expiration)



Freezer

-50° to -15°C (-58° to 5°F)

- Do not store on dry ice or below -50°C (-58°F)



Refrigerator

2° to 8°C (36° to 46°F) up to 30 days
prior to first use



Room Temperature

8° to 25°C (46° to 77°F) for a total of
24 hours

- Store in original carton to protect from light
- Do not refreeze a thawed vial

Transportation of Thawed Vials at 2° to 8°C (36° to 46°F)

- If transport at -50° to -15°C (-58° to 5°F) is not feasible, thawed vials may be transported for up to 12 hours at 2° to 8°C (36° to 46°F), under these conditions:
 - Shipped using shipping containers qualified to maintain 2° to 8°C (36° to 46°F)
- AND**
- Routine road and air transport conditions with shaking and vibration minimized
- Once thawed and transported at 2° to 8°C (36° to 46°F), vials should not be refrozen
- Thawed and transported vials should be stored at 2° to 8°C (36° to 46°F) until use

For full information on storage and handling, please see Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers).

Moderna COVID-19 Vaccine Full EUA Prescribing Information. Moderna; Updated March 29, 2022.

Slide 3

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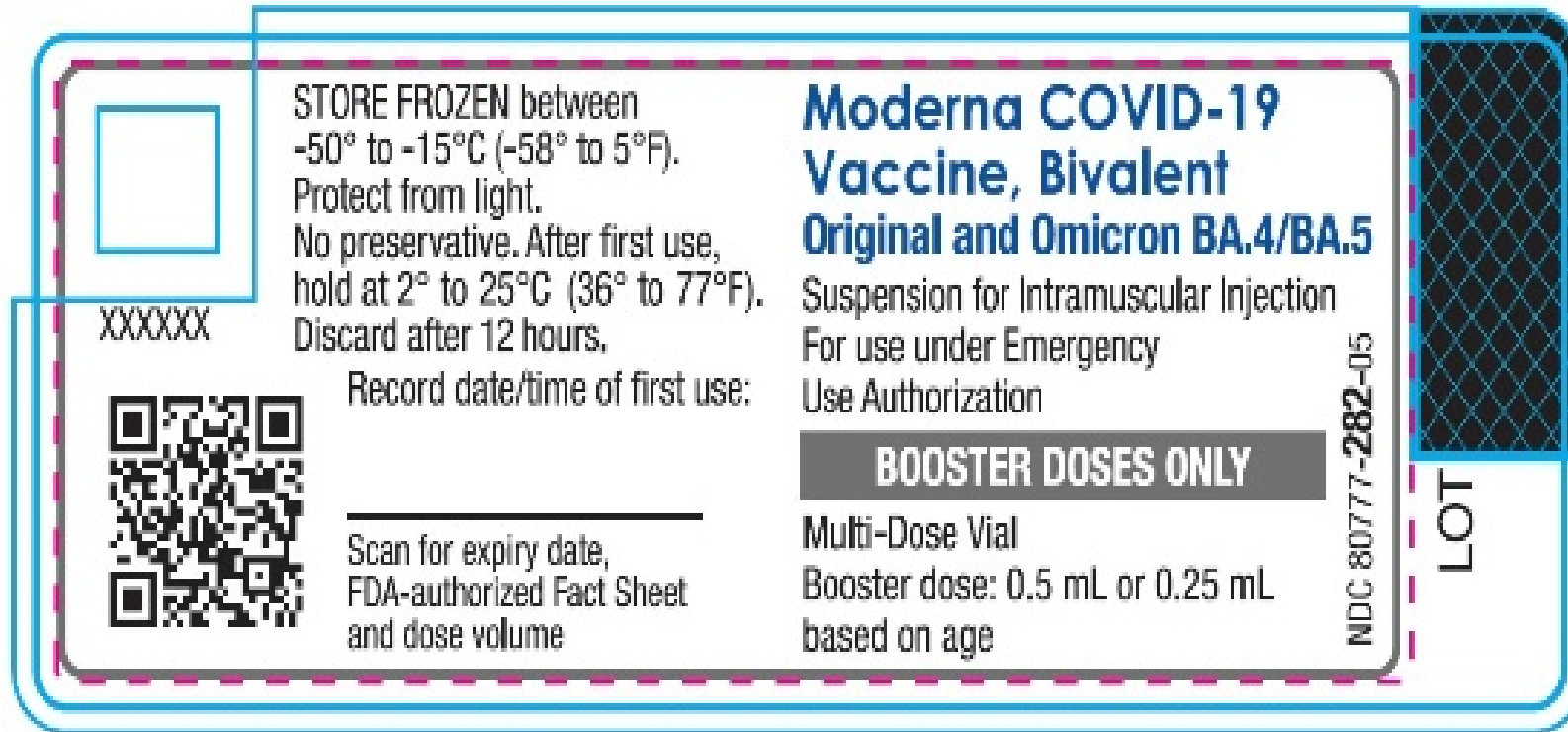
Moderna Booster Packaging

Note: Packages of Moderna will have a blue colored cap and a gray labeled border for bivalent booster vials. This is a model picture of the vial and 10-pack carton.

PRE-EUA-Current as of 9/30/2022:
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DO NOT DISTRIBUTE



Moderna Booster Vials








PRE-EUA-Current as of 9/30/2022:
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DO NOT DISTRIBUTE

Currently Available Dose Presentations – Pfizer

PRE-EUA-Current as of 9/30/2022:
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Pfizer-BioNTech Vaccine Products

	 Monovalent Product	 Monovalent Product	 Monovalent Product	 Bivalent Product	 Bivalent Product
Authorized for ages	12 years and older	5–11 years	6 months–4 years	12 years and older	5–11 years
Authorized for doses	Primary Series	Primary Series	Primary Series	Booster Dose	Booster Dose
Cap Color/Label Color	Gray Cap/ Gray Label	Orange Cap/ Orange Label	Maroon Cap/ Maroon Label	Gray Cap/ Gray Label	Orange Cap/ Orange Label
Dose (mRNA concentration)	30 mcg	10 mcg	30 mcg	30 mcg (15 mcg original, 15 mcg Omicron BA.4/BA.5)	10 mcg (5 mcg original, 5 mcg Omicron BA.4/BA.5)
Vaccine composition	Monovalent	Monovalent	Monovalent	Bivalent Original and Omicron BA.4/BA.5	Bivalent Original and Omicron BA.4/BA.5
Injection Volume	0.3 mL	0.2 mL	0.2 mL	0.3 mL	0.2 mL
Dilution Required	No	1.3 mL of diluent	2.2 mL of diluent	No	1.3 mL of diluent
Beyond-use date	12 hours after puncture				
Storage	Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks				

Pfizer Vials: Primary Series vs Booster Dose

Product Characteristics: Orange Caps – 5 Through 11 Years of Age (DILUTE BEFORE USE)

Pfizer-BioNTech COVID-19 Vaccine
Monovalent
Primary Series Only*



10 doses per vial (after dilution)

Pfizer-BioNTech
COVID-19 Vaccine, Bivalent
Booster Dose Only*



10 doses per vial (after dilution)

ALL ORANGE CAP VIALS:

- Orange vial cap and orange label border
- **DILUTE BEFORE USE** with 1.3 mL of 0.9% Sodium Chloride Injection, USP**
- 0.2 mL (10 mcg) dose

***PRELIMINARY– SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION**

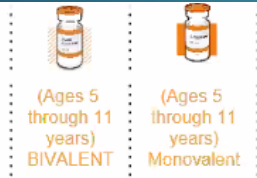
****Diluent:** ONLY use sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

FOR TRAINING PURPOSES ONLY: THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) HAS NOT BEEN AUTHORIZED FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE



Before administration, please see full Prescribing Information: 12 years of age and older or appropriate EUA Fact Sheet for Vaccination Providers. For the most recent prescribing information and fact sheets, please visit www.cvdvaccine-us.com

** Important Considerations **



- It is anticipated that the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), if authorized, will be used as the **BOOSTER DOSE** in individuals 5 through 11 years of age.
- Pfizer-BioNTech COVID-19 Vaccine will continue to be used for the **PRIMARY SERIES** in individuals 5 through 11 years of age.
- The Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), if authorized, will be supplied in multiple-dose vials with an **ORANGE** cap and **ORANGE** vial label border.



- It is important to **DIFFERENTIATE** between the two vaccine products to ensure individuals 5 through 11 years of age receive the appropriate vaccine.

FOR TRAINING PURPOSES ONLY: THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) HAS NOT BEEN AUTHORIZED FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE



Before administration, please see full Prescribing Information: 12 years of age and older or appropriate EUA Fact Sheet for Vaccination Providers. For the most recent prescribing information and fact sheets, please visit www.cvdvaccine-us.com

Avoiding COVID-19 Vaccine Errors

- ✓ Develop a plan for storing the vaccines prior to administration
- ✓ Clearly label all individual syringes containing vaccines
- ✓ Prior to administration of the vaccine, ensure the following:



Right PATIENT

- Verify patient screening information



Right TIME

- Check FDA authorized and CDC recommended intervals for doses



Right DOCUMENTATION

- Document vaccine administration per CDC guidance



Right VACCINE

- Is the cap color & colored label border correct based upon the individual's age?
- Booster dose vs. primary series?
- Does the vaccine require dilution?
- Check expiration dates and Beyond-Use-Date (BUD)



Right DOSE

- Vaccine dose is based on an individual's age
- Was the correct volume of vaccine withdrawn?



Right ROUTE

- Authorized & approved COVID-19 vaccines are intramuscular injections. Ensure correct needle length.
- Refer to CDC resources regarding vaccine administration

Sources: Adapted from National Alert Network (NAN), "Age-related COVID-19 vaccine mix-ups," Institute for Safe Medication Practices (ISMP) Dec 6, 2021. Immunization Action Coalition <https://www.immunize.org/catg.d/p3048.pdf>. Accessed Dec 13, 2021. CDC Vaccine Storage and Handling Toolkit <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html> Accessed Dec 13, 2021. Kroger, A., CDC National Center for Immunization and Respiratory Diseases. "Avoid Vaccine Administration Errors with Seven Simple Steps," Feb 2012. Accessed Jun 29, 2022.



Before administration, please see full Prescribing Information: 12 years of age and older or appropriate EUA Fact Sheet for Vaccination Providers. For the most recent prescribing information and fact sheets, please visit www.cvdvaccine-us.com

Pfizer Packaging

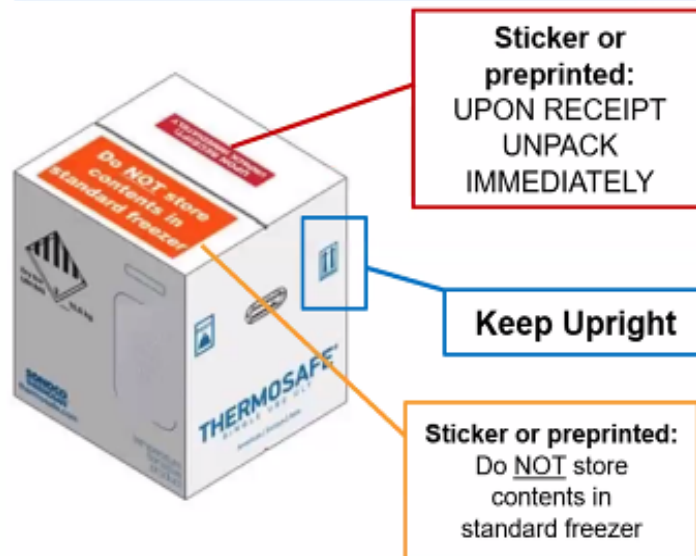
Product Packaging: Thermal Shippers

Applicable to the following cap colors:

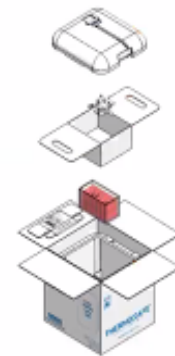
GRAY	ORANGE	MAROON
(Ages 12+) DO NOT DILUTE	(Ages 5 thru 11)	(Ages 6 month thru 4)

For more information on unpacking the medium ULT and single use thermal shipping containers, storage, handling and return of the thermal shipping container and/or temperature monitors, please see

<https://www.cvdvaccine-us.com>



SINGLE USE ● ● ●



25-PACK CARTON ●

Between 1 and 4 cartons stacked in the box that holds the vial packs.

10-PACK CARTON ● ● ●

Between 1 to 10 cartons stacked in the box that holds the vial cartons.

The Single-Use Thermal Shipping Container **cannot** be used for temporary storage.

The single use shipper should be disposed of after unpacking the vaccine. However, **the Controlant monitor will need to be returned.**

The above is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.
Read all instructions included with the thermal shipping container and its components

FOR TRAINING PURPOSES ONLY – THE VACCINE HAS NOT BEEN AUTHORIZED FOR USE IN INDIVIDUALS YOUNGER THAN 5 YEARS OF AGE



Before administration of the vaccine, please see full Prescribing Information: 16+ years of age (DILUTE BEFORE USE/Purple Cap) and 16+ years of age (DO NOT DILUTE/Gray Cap) and EUA Fact Sheets for Vaccination Providers: 12+ years of age (DILUTE BEFORE USE/Purple Cap), 12+ years of age (DO NOT DILUTE/Gray Cap) and 5 through 11 years of age (DILUTE BEFORE USE/Orange Cap). For the most recent prescribing information and fact sheets, please visit www.cvdvaccine-us.com

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Note: Doses under 100 doses will be shipped through M&D so vaccine may arrive in a different shipper than below:

Pfizer Booster Packaging



Note: real packages of Pfizer-BioNTech will have Orange-cap vials for bivalent booster vaccine. This is a model picture of the vial and 10-pack carton.

Initial Allocation

- Ordering for the new Pfizer bivalent booster dose product began on **Wednesday, October 12th**
- Depending on the quantity of provider orders, and quantity of our state allocation, your order submission may be adjusted
- The Immunization Program will make every effort to ensure every provider who orders vaccine receives vaccine in this initial roll-out

Bivalent Booster Vaccine: Minimum Order

- The minimum direct order size for Pfizer and Moderna will be a quantity of 100 doses
- **However, LDH will not require this large of a minimum order – orders less than the federal minimum will come through M&D**
- The minimum M&D order size will be a quantity of 10 doses

Initial Allocation

- Providers should prepare to receive and store doses early **but not begin administration** until full CDC and LDH authorization is given
- Booster vaccine administration start date is **the week of October 10th**
- Reminder – do not set appointments until vaccines are physically received

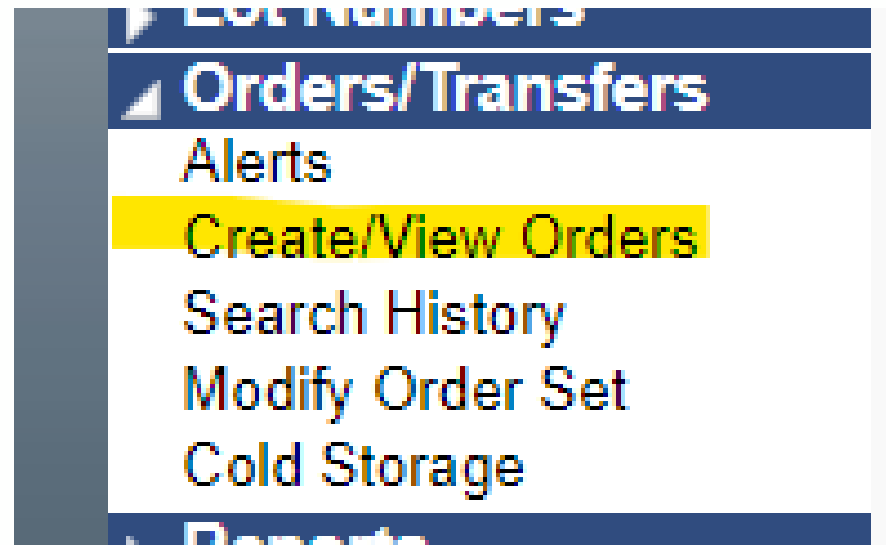
Other Planning Considerations

- Appointments for monovalent Pfizer-BioNTech or Moderna boosters in people 5-11 years of age and older must be rescheduled for when locations have the bivalent COVID-19 vaccines available.
- To support increased logistics needed to push out large number of booster doses during the first week, other vaccine products, from both the federal government and Morris and Dickson, may experience delays during initial pediatric bivalent booster rollout

COVID-19 Vaccine Order Form Walkthrough

Ordering COVID-19 Booster Vaccines Through LINKS

- Log in to LINKS
- Go to the navigation menu. Click **Orders/Transfers**, then click **Create/View Orders**.



Ordering COVID-19 Booster Vaccines Through LINKS

- Click on **Create Order**. This will bring you to your reconciliation page.
- Before you can proceed you will need to reconcile your inventory. Once completed, click **Submit Monthly Inventory**.

Reconcile										
Vaccine	Number	Quantity on Hand	Physical Inventory	Adjustment (+/-)	Category	Reason	Funding Source	Inactive	Add Row	
COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose (Covid-19 0.3 (Pfizer))	25256645	10/31/2021	10	10	0.0	--No Category Required v	--No Reason Required-- v	PUB	<input type="checkbox"/>	+
MMR	1234567	06/20/2022	10	10	0.0	--No Category Required v	--No Reason Required-- v	PUB	<input type="checkbox"/>	+

Inventory Last Submitted: 10/19/2021

Print Reset Save

Submit Monthly Inventory

Ordering COVID-19 Booster Vaccines Through LINKS

- Once you submit your monthly inventory, your Create Order page will be visible.
- Select your *Order Set* (for this case will be COVID-19 Pediatric/Distributor). Enter the *Order Quantity* (For COVID-19 pediatric vaccine, the minimum is 10 for Pfizer and 10 for Moderna). Select the *Vaccine Name*.
- Click **Submit Order**.
- It will take you to the Order/Transfer List and show; ex **Order 529475 Successfully created and Pending State Approval**. You will know your order has been completed and is awaiting approval.

Create Order
 Organization: TEST IRMS
 Facility: TEST FACILITY
 Phone Number: (318)222-6666
 Phone Extension:
 Email: ADRIENNE.MERCADEL@LA.GOV

First Name: JANE
 Middle Name:
 Last Name: PIGGY
 Address: 560 MOCCASIN LANE
 City: NEW ORLEANS
 State: LA
 Zip: 70112

Monday: ☒ 08:00 12:00 13:30 17:00
 Wednesday: ☐ 09:00 12:00 13:00 17:00
 Friday: ☐ 09:00 12:00 13:00 17:00

Tuesday: ☒ 09:00 12:00 13:30 17:00
 Thursday: ☒ 08:00 11:00 13:00 17:00

PIN: 88TEST
 Order Date: 06/09/2022
 Submitter: JUDI GREENE (JGREENE)
 Comments:
 Inventory Last Submitted: 06/07/2022
 Last Order Submitted: 06/08/2022 02:07:29 PM
 Order Set: COVID-19 PEDIATRIC / Distributor
 Inventory Transaction Report Lot Number Summary Edit Temperature

Instructions:
 Order Status: In Progress

 Order Frequency: Order Timing:
 Order Schedule:

Cancel Save Order Submit Order

Administering COVID Moderna Bi-Valent Boosters in LINKS

STEP ONE:

Go to patient search/add enter first initial of first name and DOB. Select your patient.

Patient Search Results

Records Found = 10

Search Criteria: First Name / Last Name (Exact)

Show 100 entries

Search:

First Name	Middle Name	Last Name	Birth Date	SIIS Patient ID	Grd First Name	Grd Last Name
TEST	MARIE	TEST	01/21/1981	13312217		
TEST	REAL	TEST	06/25/2005	13761292		
TEST		TEST	07/24/1984	13693024		
TEST		TEST	01/02/2022	13925173		
TEST		TEST	07/31/1986	13736774		
TEST		TEST	01/25/2000	14110640		
TEST		TEST	06/07/2019	14076530	MISSTEST	
TEST		TEST	10/12/2009	13703113		
TEST		TEST	08/12/2012	12651161		
TEST		TEST	01/01/2005	13764394		

Showing 1 to 10 of 10 entries

STEP TWO:

Go to Vaccinations>View/add

For both adult and pediatric vaccine enter the date as below:

Vaccinia, smallpox monkeypox vaccine live, PF, SQ or ID injection ((monkeypox))	
COVID-19, mRNA, LNP-S, bivalent booster, PF, 50 mcg/0.5 mL or 25mcg/0.25 mL dose (Moderna (Bi-Valent))	09/30/2022
COVID-19, mRNA, LNP-S, bivalent booster, PF, 30 mcg/0.3 mL dose (Pfizer (Bi-Valent))	
--select--	

Click "Add Administered".

STEP THREE:

Now "Click to select" on the Vaccination Detail Add page to select your lot number.

Vaccination Detail Add	
Vaccine 1:	COVID-19, mRNA, LNP-S, bivalent booster, PF, 50 mcg/0.5 mL or 25mcg/0.25 mL dose
Date Administered:	09/30/2022
Historical:	<input type="radio"/> YES <input checked="" type="radio"/> NO
Manufacturer:	Click to select
Lot Number:	

Select Lot Number						
Select	Manufacturer	Lot Number	Facility	Funding Source	Expiration Date	Doses Available Dose Volume
-->	MODERNA US, INC.	123653		PUB	08/08/2024	10.0

FOR ADULTS: The Dose Size is "Full" and Volume (CC) is 0.5.

Dose Size:	Full
Volume (CC):	0.5

FOR PEDIATRICS: The Dose Size is "Half" and Volume (CC) is 0.25.

Dose Size:	Half
Volume (CC):	0.25

Q&A