Monkeypox

Overview for Healthcare Providers

KANE COUNTY HEALTH DEPARTMENT

Monkeypox- Current Data

Confirmed Cases as of 07/06/2022-

- Globally- 7,243 confirmed cases
- U.S.- 605 confirmed cases
- Illinois- 84 confirmed cases

Sources:

https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

IDPH Siren 07/07/2022

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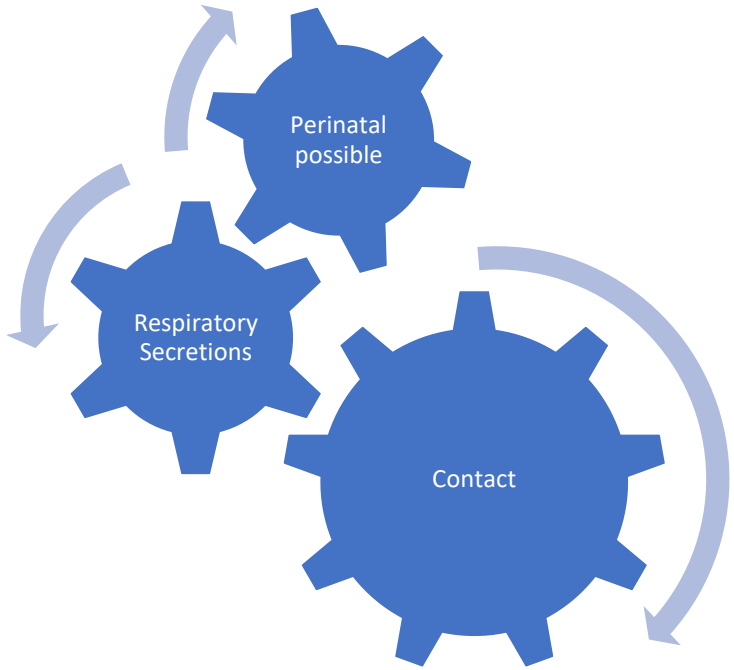
Routes of Transmission

Human-to-human transmission occurs by:

- direct contact with lesions or lesion materials (i.e. linens, towels, clothing, etc.)
- exposure to respiratory secretions
- Mother to baby transmission is possible.



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Incubation and Infectious Periods

Incubation period-

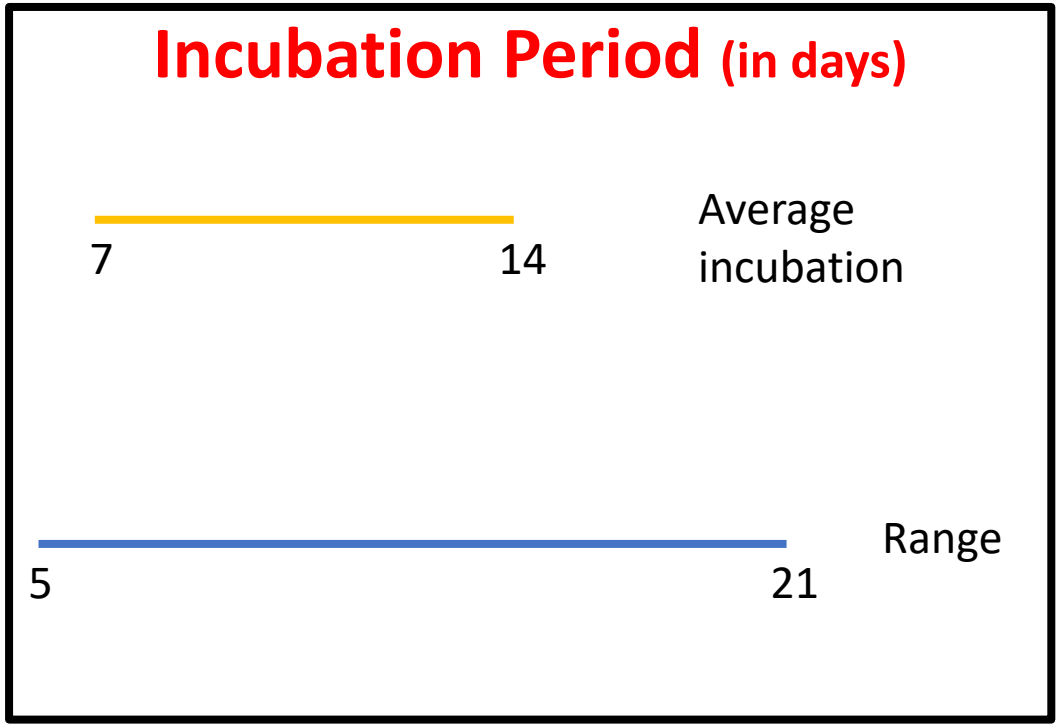
- ranges from 5-21 days with an average incubation of 7-14 days.

Infectious period-

- begins at the onset of symptoms and ends once all lesions have crusted over, fallen off and new, healthy skin is visible

Illness duration-

- typically 2-4 weeks



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Patient Assessment and Documentation

Patient History

- Did the patient have contact with a case or someone ill who had a rash? What kind of contact?
- Any travel in the past 21 days? International? Out of state? Dates of travel?
- Sexual contact in past 21 days? Type of sexual activity? Was sexual activity unprotected?
- Number of partners in past 21 days?
- Sexual orientation- gay, bisexual, or MSM?
- Patient's occupation?

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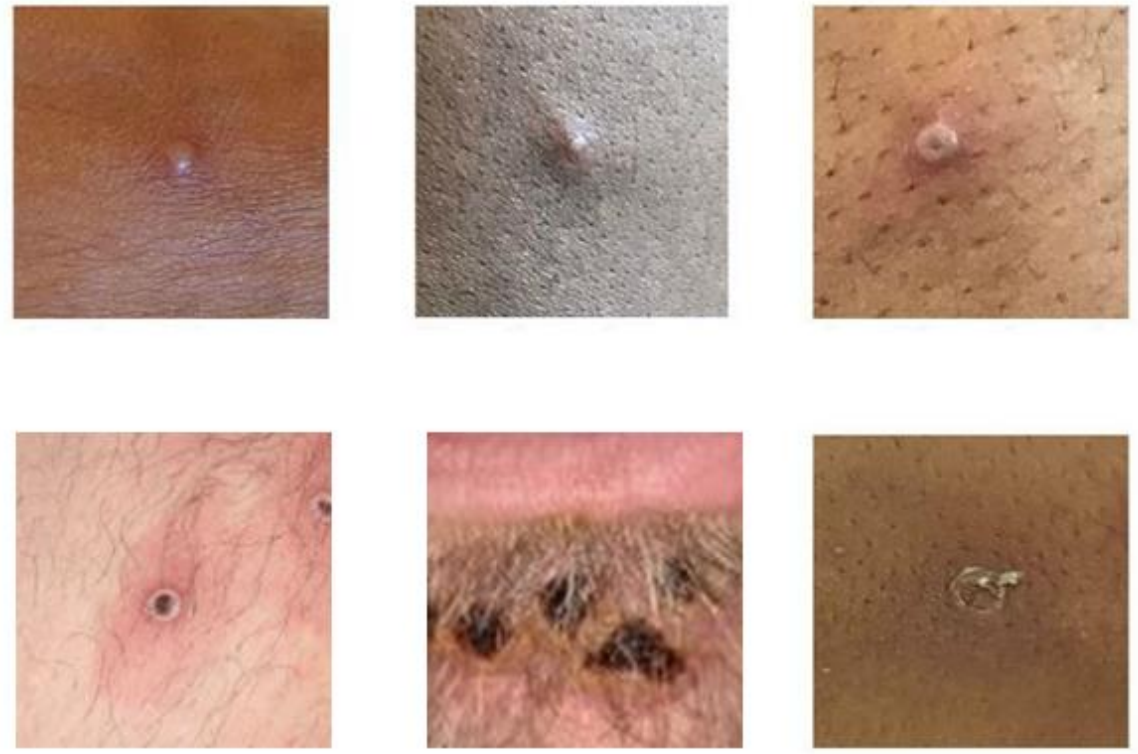
Signs and Symptoms

The patient may or may not experience prodrome prior to rash

- Fever or chills
- Headache
- Myalgia
- Lymphadenopathy
- Malaise
- Cough
- Ocular lesions or conjunctivitis
- Pruritus
- Vomiting or nausea
- Tenesmus, rectal pain or bleeding
- Pus or blood on stools
- Rash/skin lesions*



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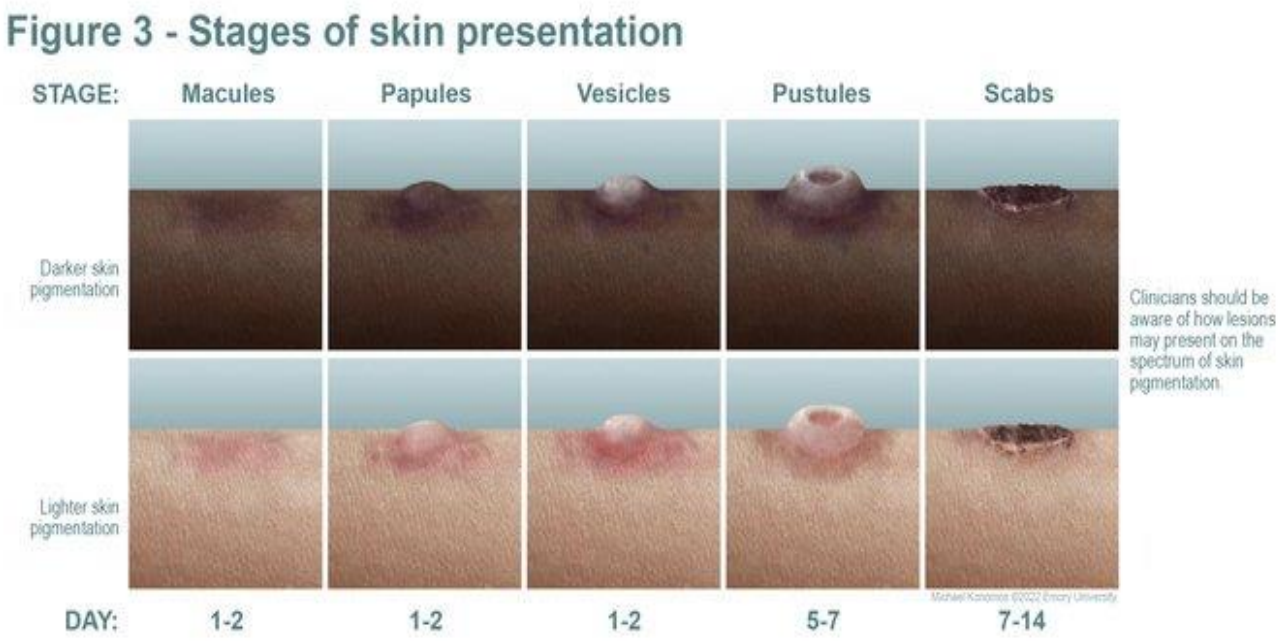
Rash/Lesions- Assessment and Documentation

Inspect all skin and mucous membranes and document the following regarding rash or skin lesions:

- macular, papular, vesicular, pustular, or ulcerated?
- Anatomical location of lesions upon exam?
- Anatomical location where patient reported lesions first appeared? Date of onset?
- Well-differentiated?
- Deep-seated?
- Umbilicated?
- In the same stage in each anatomical location?
- Similar in size?
- **Take pictures of lesions for IDPH testing approval**



Reporting Suspect Cases

Clinicians should immediately report any suspect Kane County cases

- Follow the IDPH Monkeypox Suspect Case Checklist
- Provide KCHD with health care facility's preferred contact person and phone numbers of the contact person
- Take appropriate infection control precautions immediately.

Kane County Health Department

630-208-3801

24/7 emergency number

KANE COUNTY HEALTH DEPARTMENT

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH
525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Monkeypox Suspect Case Checklist

Patient Precautions

Have suspect patient wear a mask and cover any exposed skin lesions prior to arrival
Do not place suspect patient in general waiting area
Place suspect patient directly into a closed, single-person room with a dedicated toilet

Healthcare Personnel Precautions

Prior to seeing a suspect patient, healthcare personnel should don:
- Gown
- Gloves
- Eye protection
- N95 or higher level respirator mask

Pregnant or immune-compromised staff should avoid interacting with suspect patients

Patient History and Presentation

Determine if, in the last 21 days, they have:
- Had contact with anyone with a rash or confirmed/probable monkeypox
- Had close in-person contact with any men who have sex with men
- Traveled outside the US
- Had contact with a dead or live wild animal or exotic pet endemic to Africa

Examine patient for deep-seated and well-circumscribed lesions, often with central umbilication
Take a picture of the rash if possible

If the rash is characteristic or the patient meets any of the exposure criteria above and has symptoms of monkeypox, contact your local health department prior to collecting diagnostic specimens

Infection Control Measures

Patient Placement

- Place in a single-person room with a dedicated bathroom (special air handling is not required).
- The door should be kept closed (if safe to do so).
- Tag door with required transmission-based precautions (TPB).
- Transport and movement of the patient outside of the room should be limited to medically essential purposes.
- If the patient is transported outside of their room, the patient should use well-fitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown.
- **Intubation, extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room.**

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Personal Protective Equipment (PPE)

PPE for all healthcare facility personnel who enter the patient's room should include:

1. Gown
2. Gloves
3. Eye protection (i.e., goggles or a face shield that covers the front and sides of the face)
4. NIOSH-approved particulate respirator equipped with N95 filters or higher

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Waste Management

Waste management (i.e., handling, storage, treatment, and disposal of soiled PPE, patient dressings, etc.)

- should be performed in accordance with U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR; 49 CFR, Parts 171-180.)

Required waste management practices and category designation can differ depending on the monkeypox virus clade (strain).

- See the DOT website for more information.

Facilities should also comply with state and local regulations for handling, storage, treatment, and disposal of waste.

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Environmental Infection Control

Standard cleaning and disinfection

- Use a EPA-registered hospital-grade disinfectant with an **Tier 1 emerging viral pathogen claim**. See EPA's Disinfectants for Emerging Viral Pathogens List Q.
- Follow the manufacturer's directions for concentration, contact time, and care and handling.

Soiled laundry (e.g., bedding, towels, personal clothing)

- Avoid contact with lesion material that may be present on the laundry.
- Soiled laundry should be gently and promptly contained in an appropriate laundry bag - never shaken or handled in manner that may disperse infectious material.

Activities such as dry dusting, sweeping, or vacuuming should be avoided. **Wet cleaning methods are preferred.**

Management of food service items should be performed with routine procedures.

EPA United States Environmental Protection Agency

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Duration of Precautions

Medical providers should work with Kane County Health Department to determine discontinuation of isolation precautions and patient release from isolation.

Isolation precautions should be maintained until <u>all lesions</u> have crusted, those crusts have separated, and a fresh layer of healthy skin has formed underneath.

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Testing and Specimen Collection- IDPH Labs

Step 1: Testing Approval

Clinicians should promptly report any suspect Kane county cases to the Kane County Health Department for testing approval.

If monkeypox testing is approved:

- Testing is performed on a **dry** swab of vesicles/pustules, lesion crust, or tissue biopsy at the IDPH laboratories (throat swabs, touch prep slides of lesions) – but should be discussed with IDPH in advance of submitting).
- **4 total specimens must be collected (two specimens should be collected per lesion from 2 different anatomic sites**).
- Orthopox positive specimens at IDPH labs will be sent to CDC labs for monkeypox-specific testing.
- **Specimens should not be submitted to IDPH without health department approval.**

4 specimens required

- ✓ 2 specimens per lesion
- ✓ 2 different anatomical sites

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Testing and Specimen Collection- IDPH Labs

Step 2: Specimen Collection Methods

- Specimen collection can occur in outpatient or inpatient settings.
- Personal protective equipment (PPE) for specimen collection- gown, gloves, eye protection (e.g. goggles or a face shield that covers the front and sides of the face), and a NIOSH-approved particulate respirator equipped with N95 filters or higher.
- Collect specimen in a single-person room, with the door closed (if safe to do so). Special air handling is not required.
- Use a sterile nylon, polyester, or Dacron swab with a plastic or thin aluminum shaft. Do not use other types of swabs. Do not use swabs contained within a media transport system (e.g. ESwab). **A dry swab is currently the only acceptable specimen approved for testing.**
- Vigorously swab or brush lesion. If the skin atop the vesicle or pustule is intact, it may be necessary to gently lance and lift the lesion.
- Collect from two lesions from different locations on the body and/or from lesions with differing appearances. **Use a new swab for each specimen.** There should be at least four specimens – at least two lesions with two specimens per lesion. Each specimen should be stored in its own container.
- Place each specimen in a separate sterile container (e.g., by breaking off end of applicator of each swab into a 1.5 or 2-mL screw-capped tube with O-ring, placing in a sterile urine cup, or15cc/50cc conical tube). **Do not add or store in viral, universal, or other transport media.**

✓ Use a dry swab with no media.
✓ Use a new swab for each specimen.

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Testing and Specimen Collection- IDPH Labs

Label each specimen container with:

- Patient Name and Date of Birth
- Medical Record Number
- Lesion Location. Label duplicates A and B (e.g., left thigh A, left thigh B; perianal A, etc.); if multiple specimens are collected from the same site, number and label them (e.g., Lesion 1. perianal 1A, Lesion 1. perianal 1B, Lesion 2. perianal 2A, Lesion 2. perianal 2B).
- Collection date

<u>Refrigerate (2-8°C) or freeze (≤ -20°C) within an hour of collection.</u>

- Refrigerated specimens may be stored up to 7 Days.
- Frozen specimens may be stored up to 60 Days.

Refrigerate (2-8 °C) or
Freeze (≤ -20°C)
specimen within 1 hour of collection

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Testing and Specimen Collection

Step 3: Lab Requisition Forms

Requisition forms: There should be at least four specimens (at least two per lesion from two separate lesions). Complete a IDPH Communicable Disease Laboratory Test Requisition Form for each of the four specimens.

- No authorization code is required.
- **Under Test Request Information, select "Orthopoxvirus" and write OPX on the"*Other Test" line.**
- For Source/Specimen type, select the appropriate specimen type (e.g., skin, genital swab) and specify the exact lesion location (e.g., right foot, abdomen, left thigh) on the "**Other Source" line.
- **All patient Information MUST be identical to labels on the specimen containers or the specimens will be rejected from testing.**
- **Be sure to complete the form in its entirety.**

Complete a IDPH Communicable Disease Laboratory Test Requisition Form for each of the four specimens.

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State of Illinois
Illinois Department of Public Health

Communicable Diseases Laboratory Test Requisition

Authorization Code:_____
(if applicable)

REQUISITION MUST BE FILLED OUT COMPLETELY

Laboratory Specimen Number
(FOR PUBLIC HEALTH USE ONLY)

Type or use indelible dark ink and print legibly with capital letters

Outbreak #:

SUBMITTER INFORMATION:_____
Submitting Institution

_____ _____ _____ _____
Submitter Address (Street Number, Name of Street) | City | State | ZIP Code

_____ _____ _____ _____
Contact Person/Clinician's Last Name | Telephone Number | FAX | E-mail Address

PATIENT INFORMATION:

_____ _____ _____
Patient's Last Name | First Name | Middle Name

_____ _____
Street Address | Apartment/Suite Number

_____ _____ _____
City | State | ZIP Code

_____ _____ _____
Telephone Number | Birthday (mm/dd/yyyy) | Age

Sex
❑ Male
❑ Female

Race
❑ White
❑ African American/ Black
❑ Native American
❑ Asian/Pacific Islander
❑ Other/Unknown

Ethnicity
❑ Hispanic
❑ Non-Hispanic

Patient ID # (optional) _____ Medicaid Recipient ID # _____

TEST REQUEST INFORMATION When sending acute and convalescent serology specimens, use one test requisition. Complete collection information immediately below for acute specimen and complete collection information for convalescent specimen in the "Source/Specimen Type" box.

_____ _____:_____ ( ) a.m. _____ Initials of Person _____ Initials of Person _____
Date Collected (mm/dd/yyyy) | Time collected ( ) p.m. | Date of Onset | Collecting Specimen | Completing Form

TEST		SOURCE/ SPECIMEN TYPE (one source type per form)		REASON
❑ Arbovirus Panel ❑ B. Strep (Gp A) ❑ B. Strep (Gp B) ❑ Bacillus anthracis ❑ Brucella ❑ Burkholderia ❑ Cyclospora ❑ Cryptosporidium ❑ Francisella ❑ Gonorrhea Culture ❑ Giardia ❑ Legionella ❑ Malaria PCR ❑ Measles PCR ❑ Mumps PCR ❑ MTBC Smear, Cult, ID & Sensitivity	❑ MTBC – PCR (Resp. spec. only) ❑ MTB Genotyping only ❑ Norovirus ❑ Orthopox virus ❑ Respiratory Panel ❑ Salmonella ❑ Shiga-toxin producing E. coli or E. coli O157 ❑ Shigella ❑ Staphylococcus aureus ❑ Varicella-zoster ❑ Yersinia ❑ Yersinia pestis ❑ Vibrio ❑ Other (Specify Below*)	❑ Anterior Nasal ❑ Blood - Film ❑ Blood - Serum ❑ Blood - Whole ❑ Body Fluid (Specify Below**) ❑ Bronchial Alveolar Lavage "BAL" ❑ Bronchial Washing ❑ Fecal Swab ❑ Genital Swab ❑ Nasal Aspirate ❑ Nasopharyngeal Swab ❑ O&P Kit ❑ Oropharyngeal Swab ❑ Pharyngeal Swab ❑ Rectal Swab ❑ Referred/Isolated Culture	❑ Serum – Acute ❑ Serum - Convalescent ❑ Skin ❑ Smear ❑ Spinal Fluid ❑ Stool/Feces ❑ Sputum ❑ Tissue Culture Fluid ❑ Tissue (Specify Below**) ❑ Throat Swab ❑ Urine ❑ Vaginal Swab ❑ Other (Specify Below**) ❑ Other Swab (Specify Below**)	❑ Carrier ❑ Confirmation ❑ Contact ❑ Diagnosis ❑ Foodborne Illness ❑ Immunity ❑ Outbreak ❑ Post Vaccination ❑ Release Specimen ❑ Routine Screening ❑ Rule Out Threat Agent ❑ Symptomatic ❑ Treatment ❑ Typing ❑ Other (Specify Below***)

_____ _____
*OTHER TEST | **SOURCE

_____
***REASON(S)

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Testing via Labcorp

As of 7/6/2022, Labcorp is running the FDA-cleared, PCR-based orthopoxvirus DNA assay developed by the CDC.

- No approval is needed for testing

Test details:

- Order code: 140230
- Turnaround time: 2-3 days from specimen pickup.
- Sample collection: Vigorously swab or brush the base of the lesion with a sterile dry polyester, rayon or Dacron swab. Collect a second swab from the same lesion. Insert both swabs into the sterile plastic aliquot tube or sleeve and break off the end of the swabs, if required, to tightly close the sample. Do not add any transport media to the sample. Two swabs should be submitted to ensure adequate material is sampled.
- The test sample must be collected by a clinician at the site where the patient is being seen. Labcorp cannot collect this sample at a patient service center.
- The uncovered costs of testing at commercial labs may also be considered in determining testing priorities at IDPH laboratories.

Interim Clinical Guidance for the Treatment of Monkeypox

Patients who should be considered for treatment following consultation with CDC might include:

- People with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- People who may be at high risk of severe disease:
  - ✓ People with immunocompromise (e.g., human immunodeficiency virus/acquired immune deficiency syndrome infection, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component)
  - ✓ Pediatric populations, particularly patients younger than 8 years of age
  - ✓ People with a history or presence of atopic dermatitis, persons with other active exfoliative skin conditions (e.g., eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease [keratosis follicularis])
  - ✓ Pregnant or breastfeeding women
  - ✓ People with one or more complications (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)
- People with monkeypox virus aberrant infections that include accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)

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Contacts of a Suspect Monkeypox Case

Obtain the following information for staff/patients/loved ones that had contact with the suspect case while at the healthcare facility and report to Kane County Health Department:

1. Date(s) of contact
2. Name
3. Date of birth
4. Address
5. Phone number
6. Description of interaction with suspect case (i.e. collected specimens, registered patient, put on patient wristband, provided exam, etc.)
7. Estimated length of time of exposure to patient
8. PPE worn during exposure (i.e. gloves, type of mask, gown, eye protection/face shield)

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Contact's Exposure Risk	Contact's Condition(s) of Exposure	CDC Recommendation for Contacts
High	• Unprotected contact between a person's skin or mucous membranes and the skin, lesions, or bodily fluids from a patient (e.g., any sexual contact, inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) **-OR-** • Being inside the patient's room or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection **-OR-** • Exposure that, at the discretion of public health authorities, was recategorized to this risk level (i.e., exposure that ordinarily would be considered a lower risk exposure, raised to this risk level because of unique circumstances)	• Post-exposure prophylaxis (PEP) ** ➢ Provided within 4 days of exposure for <u>prevention</u> of infection ➢ Provided 4-14 days after exposure can <u>reduce risk of serious disease</u> • Public health monitoring for 21 days after last exposure
Intermediate	• Being within 6 feet for 3 hours or more of an unmasked patient without wearing, at a minimum, a surgical mask **-OR-** • Activities resulting in contact between sleeves and other parts of an individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown **-OR-** • Exposure that, at the discretion of public health authorities, was recategorized to this risk level because of unique circumstances (e.g., if the potential for an aerosol exposure is uncertain, public health authorities may choose to decrease risk level from high to intermediate)	• PEP – Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks • Public health monitoring for 21 days after last exposure
Low	• Entered the patient room without wearing eye protection on one or more occasions, regardless of duration of exposure **-OR-** • During all entries in the patient care area or room (except for during any procedures listed above in the high-risk category), wore gown, gloves, eye protection, and at minimum, a surgical mask **-OR-** • Being within 6 feet of an unmasked patient for less than 3 hours without wearing at minimum, a surgical mask **-OR-** • Exposure that, at the discretion of public health authorities, was recategorized to this risk level based on unique circumstances (e.g., uncertainty about whether Monkeypox virus was present on a surface and/or whether a person touched that surface)	• PEP- None • Public health monitoring for 21 days after last exposure

Post-Exposure Prophylaxis (PEP) for Contacts

CDC recommends that PEP be given:

- **within 4 days from the date of exposure in order to prevent onset of the disease.**
- **If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.**
- PEP is recommended for those with high exposure risk.
- For those with intermediate exposure risk, informed clinical decision making is recommended on an individual basis to determine whether benefits of PEP outweigh risks.

PEP-

Post-exposure Prophylaxis

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Medical Countermeasures Available for the Treatment of Monkeypox

Currently there is no treatment approved specifically for monkeypox virus infections.

- However, antivirals developed for use in patients with smallpox may prove beneficial against monkeypox.
- The following medical countermeasures are currently available from the Strategic National Stockpile (SNS) as options for the treatment of monkeypox unless otherwise indicated.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

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Tecovirimat (also known as TPOXX, ST-246)

TPOXX is an antiviral medication that is:

- approved by the United States Food and Drug Administration (FDA) [PDF – 24 pages] for the treatment of smallpox in adults and children.
- Data are not available on the effectiveness of tecovirimat in treating monkeypox infections in people, but studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by orthopox viruses.
- Clinical trials in people showed the drug was safe and had only minor side effects.
- CDC holds an expanded access protocol or EA-IND (sometimes called “compassionate use”) that allows for the use of stockpiled tecovirimat to treat monkeypox during an outbreak.
- Tecovirimat is available as a pill or an injection. For children who weigh less than 28.6 pounds, the capsule can be opened, and medicine mixed with semi-solid food.

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Vaccinia Immune Globulin Intravenous (VIGIV)

VIGIV

- VIGIV is licensed by FDA [PDF – 18 pages] for the treatment of complications due to vaccinia vaccination including eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, vaccinia infections in individuals who have skin conditions, and aberrant infections induced by vaccinia virus (except in cases of isolated keratitis).
- CDC holds an expanded access protocol that allows the use of VIGIV for the treatment of orthopoxviruses (including monkeypox) in an outbreak.
- Data are not available on the effectiveness of VIGIV in treatment of monkeypox virus infection.
- Use of VIGIV has no proven benefit in the treatment of monkeypox and it is unknown whether a person with severe monkeypox infection will benefit from treatment with VIGIV. However, healthcare providers may consider its use in severe cases.
- VIGIV can be considered for prophylactic use in an exposed person with severe immunodeficiency in T-cell function for which smallpox vaccination following exposure to monkeypox virus is contraindicated.

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Cidofovir (also known as Vistide)

Cidofovir is an antiviral medication that is approved by the FDA [PDF – 6 pages] for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS).

- Data is not available on the effectiveness of Cidofovir in treating human cases of monkeypox. However, it has shown to be effective against orthopoxviruses in *in vitro* and animal studies.
- CDC holds an expanded access protocol that allows for the use of stockpiled Cidofovir for the treatment of orthopoxviruses (including monkeypox) in an outbreak.
- It is unknown whether or not a person with severe monkeypox infection will benefit from treatment with Cidofovir, although its use may be considered in such instances.
- Brincidofovir may have an improved safety profile over Cidofovir. Serious renal toxicity or other adverse events have not been observed during treatment of cytomegalovirus infections with Brincidofovir as compared to treatment using Cidofovir.

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Brincidofovir (also known as CMX001 or Tembexa)

Brincidofovir is an antiviral medication that was approved by the FDA [PDF – 21 pages] on June 4, 2021 for the treatment of human smallpox disease in adult and pediatric patients, including neonates.

- Data is not available on the effectiveness of Brincidofovir in treating cases of monkeypox in people.
- However, it has shown to be effective against orthopoxviruses in *in vitro* and animal studies.
- **CDC is currently developing an EA-IND to help facilitate use of Brincidofovir as a treatment for monkeypox. However, Brincidofovir is not currently available from the SNS.**

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Expanded Access of Investigational New Drug (EA-IND) Paperwork and Reporting

The EA-IND protocol will be provided to healthcare providers at the time of clinical consult when tecovirimat therapy is indicated.

Minimally required forms to be completed and returned to CDC include:

- **Informed Consent form-** obtained ***prior to treatment initiation***
- **FDA Form 1572**—To be completed by the responsible clinician/healthcare provider overseeing the patient's treatment. Please return within 3 calendar days of treatment initiation along with a CV of the treating physician.
- **Patient Intake form-** to provide patient's baseline condition at the time of treatment decision. Complete the sections/fields that are applicable to the patient. If any CBC and/or clinical laboratory was already done as part of patient's work up, including a copy would suffice.
- **Adverse Event form-** to report whether any adverse event(s) occurred during treatment. Return to CDC at the end of patient's treatment course. Life-threatening or serious adverse events during therapy should be reported within 24 hours of occurrence or as soon as possible.
- **Clinical Outcomes form-** to report treatment duration and patient's clinical outcome upon completion of treatment.
- Photos of lesions, to the extent possible: at least 1 prior to treatment and 1 during treatment (between days 7 and 14) with dates of the photo(s) indicated.

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Summary- Provider Steps

- ✓Complete IDPH Assessment Checklist
- ✓Take pictures of lesions
- ✓Isolate Patient and ensure staff are in full PPE
- ✓Report suspect case to KCHD
- ✓Collect approved specimens per instructions and arrange transport as needed
- ✓Identify contacts at healthcare facility
- ✓Educate patient to isolate at home (if not admitted) pending lab results
- ✓Ensure patient knows they have been tested for monkeypox and to expect a call from KCHD staff for additional information.

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Monkeypox Vaccination

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Acronyms & Definitions For Prophylaxis Treatment

PEP - Post-Exposure Prophylaxis –

- refers to the vaccination of named contacts of identified cases in occupational and community settings.

PrEP - Pre-Exposure Prophylaxis –

- administering vaccine to someone at high occupational risk for monkeypox according to ACIP guidance2 (for example, laboratory workers who handle monkeypox specimens, select clinicians, and response team members), not advised by CDC at this time

“individual-directed PEP”, or “expanded PEP” or “PEP plus-plus” or “PEP++” –

- refers to expanded post-exposure prophylaxis, and is vaccination of gay, bisexual, and other men who have sex with men (cisgender or transgender) ages 18 and older and who have had multiple or anonymous sex partners or engaged in high-risk sexual activities in the past 14 days.
  - Examples of high-risk activities include attending venues for sexual contact such as bath houses, sex clubs, parties, using online dating/ hookup apps; engaging in sex work; exchanged sex for money or drugs.
  - Reaching out to people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox.

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Vaccine Strategies to Prevent Monkeypox

When administered before or after a recent exposure, vaccines can be effective tools at protecting people against monkeypox illness.

For the current outbreak, this expanded approach can be considered as "individual-directed PEP" for monkeypox; public health officials refer to it as "expanded PEP" or "PEP plus-plus" or "PEP++".

PEP++:

- People with certain risk factors are more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox. When coupled with self-isolation and other prevention measures when symptoms first occur, PEP++ may help slow the spread of the disease in areas with large numbers of monkeypox cases—which would suggest a higher level of monkeypox virus transmission.

Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP):

- This approach refers to administering vaccine to someone at high risk for monkeypox (for example, laboratory workers who handle specimens that might contain monkeypox virus). At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.

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Vaccination

CDC does not recommend widespread vaccination against monkeypox at this time.

Vaccination may be recommended for some people who:

- Are close personal contacts of people with monkeypox
- May have been exposed to the virus
- May have increased risk of being exposed to the virus, such as people who perform laboratory testing to diagnose monkeypox
- People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine.

KANE COUNTY HEALTH DEPARTMENT

Vaccines

Two vaccines licensed by the U.S. Food and Drug Administration (FDA) are available for preventing monkeypox infection:

1. JYNNEOS™
   - (also known as Imvamune or Imvanex) Vaccine
2. ACAM2000 Vaccine

KANE COUNTY HEALTH DEPARTMENT

Kane County will not be supplied with or give the ACAM2000 Vaccine at this time

KANE COUNTY HEALTH DEPARTMENT

ACAM2000 Monkeypox Vaccine

- There is an ample supply of ACAM2000
- This vaccine should not be used in people who have some health conditions: a weakened immune system, skin conditions like atopic dermatitis/eczema, or pregnancy
- People are considered fully vaccinated 4 weeks after receiving ACAM2000
- People who get vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.
- To better understand the protective benefits of these vaccines in the current outbreak, CDC will collect data on any side effects and whether the way the person was infected makes any difference in how well the vaccine protects them.

KANE COUNTY HEALTH DEPARTMENT

PEP- JYNNEOS and ACAM2000

	JYNNEOS	ACAM2000
Vaccine virus replication	Non-replicating, live virus	Replication-competent, live virus
Number of doses	2 doses given 28 days apart	1 dose
Vaccine administration	Subcutaneous injection	Percutaneous, multiple puncture technique with bifurcated needle
Ages	Currently licensed for those18 years and older; CDC working on EA-IND for children <18.	PEP for adults and children
Recommended for immunocompromised	Yes	No
Inoculation lesion or "Take" occurs on skin	No	Yes
Inadvertent inoculation and autoinoculation	No risk	Risk exists
Precautions needed to prevent potential spread	No	Yes
Considered vaccinated	2 weeks after second dose	Within 28 days of administration

KANE COUNTY HEALTH DEPARTMENT

Current Uses for JYNNEOS™

- Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
- Presumed contacts who may meet the following criteria:
  - Know that a sexual partner in the past 14 days was diagnosed with monkeypox
  - Had multiple sexual partners in the past 14 days in a jurisdiction with known monkeypox
- JYNNEOS™ doses should be prioritized for those people who are at risk for severe adverse events or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions).

KANE COUNTY HEALTH DEPARTMENT

Storage and Handling of JYNNEOS™

The vaccine is shipped frozen at -25° C to 15°C (-13°F to +5°F)

The receiving location (Kane County Health Department) will receive instructions regarding:

- How to shut the temperature monitoring devices off
- The need to send pictures of the device back to SNS so that they can release the vaccine for use based on the temperature readings
- How to return the temperature monitoring devices and empty shipping containers to the SNS
- If received at -25°C to -15°C (-13°F to +5°F) (frozen temperatures) and moved to -25°C to -15°C (-13°F to +5°F) storage conditions (freezer) immediately, vaccine may be stored until the expiration date listed on the box.

KANE COUNTY HEALTH DEPARTMENT

JYNNEOS™ Vaccine Storage

- Once thawed, do not refreeze.
- If received thawed at 2-8° Celsius (36° to 46° Fahrenheit) (refrigerated temperatures) or if it is later stored at 2-8° Celsius (36° to 46° Fahrenheit), it may be stored for up to 8 weeks.
- Please note that the information regarding the beyond-use-date when stored at 2° to 8° Celsius (36° to 46° Fahrenheit) (refrigerated temperatures) differs between the package insert and the CDC documentation
- Package insert states that the storage time is **12 hours**
- CDC-provided documentation states that the storage time is **8 weeks**
- The information in the CDC documentation supersedes the information in the package insert

KANE COUNTY HEALTH DEPARTMENT

JYNNEOS™ Vaccine Transport

- If vaccine needs to be transported, consult CDC's Vaccine Storage and Handling Toolkit for information on acceptable systems for transport to off-site clinics, satellite facilities, or for relocation of stock.
- Portable vaccine refrigerator or freezer
- Qualified container and packout
- Do not transport vaccine at frozen temperatures if it was stored at refrigerated temperatures at the originating facility.
- If vaccine is transported at refrigerated temperatures or if it begins to thaw during transit, the recipient facility should not refreeze it.
- A digital data logger must be used during transport.

KANE COUNTY HEALTH DEPARTMENT

JYNNEOS™ Preparation and Administration

1. Allow the vaccine to thaw and reach room temperature 20°C-25°C (68°F-77°F) before use.
2. Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 12 hours
3. Package insert states that the storage time is 12 hours
4. CDC-provided documentation states that the storage time is 8 weeks. The information in the CDC documentation supersedes the information in the package insert
5. Do not refreeze.
6. When thawed, JYNNEOS™ is a milky, light yellow to pale white-colored suspension.
7. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.
8. Swirl the vial gently before use for at least 30 seconds.
9. Withdraw a dose of 0.5 mL into a sterile syringe for injection.
10. Administer JYNNEOS™ by subcutaneous injection, preferably into the upper arm (deltoid).
11. People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine.

KANE COUNTY HEALTH DEPARTMENT

JYNNEOS™ Administration

- Currently licensed for those18 years and older
- Series of two subcutaneous injections (0.5 mL each) 4 weeks apart
- The immune response takes 2 weeks after the second dose for maximal development
- JYNNEOS™ is a suspension for injection that comes in 20 vials per box, each dose (0.5 mL) is supplied in a single-dose vial
- JYNNEOS™ is a sterile vaccine formulated without preservatives. The vial stoppers are not made with natural rubber latex.
- People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine.
- The effectiveness of JYNNEOS™ against monkeypox is supported by animal studies.
- There are no data on the efficacy of JYNNEOS™ for PEP or PrEP from the current outbreak.

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JYNNEOS™ Administration

- Safe for administration to people with HIV and atopic dermatitis.
- There are no data in people who are pregnant or breastfeeding, but animal data do not show evidence of reproductive harm; pregnancy and breastfeeding are not contraindications.
- Booster doses are recommended every 2 or 10 years if a person remains at continued risk for exposure to smallpox, monkeypox, or other orthopoxviruses. Your health care provider can give you more information.

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JYNNEOS™ Administration

- Smallpox/monkeypox vaccine (JYNNEOS™) may be given at the same time as other vaccines
- Certain people at increased risk of a condition called myocarditis (swelling of the heart muscle), including adolescent or young adult males
- These people might consider waiting 4 weeks after JYNNEOS™ vaccination before getting an mRNA COVID-19 vaccine
- Consult with your health care provider if you are at increased risk for myocarditis

KANE COUNTY HEALTH DEPARTMENT

JYNNEOS™ Warnings and Precautions

- Severe Allergic Reactions Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS™
- Persons who experienced a severe allergic reaction following a previous dose of JYNNEOS™ or following exposure to any component of JYNNEOS™ may be at increased risk for severe allergic reactions after JYNNEOS™ .
- The risk for a severe allergic reaction should be weighed against the risk for disease due to smallpox or monkeypox.
- Altered Immunocompetence or Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS™
- Limitations of Vaccine Effectiveness Vaccination with JYNNEOS™ may not protect all recipients.
- People with a severe allergy to any component of the vaccine (**gentamicin, ciprofloxacin, egg protein**) should not receive this vaccine.

KANE COUNTY HEALTH DEPARTMENT

Assessment Before Providing the JYNNEOS™ Vaccine

Ask the person receiving the vaccine:

1. Have they had an allergic reaction after a previous dose of smallpox vaccine
2. Do they have:
    - any severe, life threatening allergies
    - a weakened immune system
    - is pregnant or thinks they might be pregnant or
    - is breastfeeding In some cases,

1. Your health care provider may decide to postpone routine (pre-exposure) smallpox/ monkeypox vaccination with JYNNEOS™ until a future visit.
2. People with minor illnesses, such as a cold, may be vaccinated.
3. People who are moderately or severely ill should usually wait until they recover before getting a routine (pre-exposure) dose of JYNNEOS™.
4. If you have been recommended to receive JYNNEOS™ due to an exposure to monkeypox virus, you should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.

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JYNNEOS™ Adverse Reactions and Precautions

- Adverse reactions include injection site reactions such as pain, redness, soreness, swelling, and itching where the shot is given are the most common complaints after the vaccination
- Fatigue (tiredness), headache, and muscle pain can also sometimes happen after vaccination
- People with a severe allergy to any component of the vaccine (**gentamicin, ciprofloxacin, egg protein**) should not receive this vaccine.
- Safe for administration to people with HIV and atopic dermatitis.
- While there are no data in people who are pregnant or breastfeeding, animal data do not show evidence of reproductive harm; pregnancy and breastfeeding are not contraindications.

KANE COUNTY HEALTH DEPARTMENT

Adverse / Serious Reactions

Allergic reactions could occur after the vaccinated person leaves the clinic.

- Instruct the patient if there are signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), to call 9-1-1 and get the person to the nearest hospital.
- For other signs that concern you, call your health care provider.
- Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

KANE COUNTY HEALTH DEPARTMENT

References

- Centers for Disease Control and Prevention https://www.cdc.gov/
- Vaccine Information Statement Smallpox/Monkeypox (JYNNEOS™):What You Need to Know https://www.immunize.org/vis/vis_smallpox_monkeypox.asp

KANE COUNTY HEALTH DEPARTMENT

Monkeypox Vaccine Survey for Healthcare Providers

Please complete the monkeypox vaccine survey at the link below:

https://redcap.link/q1yfuknq

The link will be sent out via email after today's webinar.

KANE COUNTY HEALTH DEPARTMENT

KCHD Contact Information

Monkeypox Reporting Questions

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Monkeypox Vaccine Questions

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Q & A Session

KANE COUNTY HEALTH DEPARTMENT