Acute, Generalized Vesicular or Pustular Rash Illness Testing Protocol in the United States

Introduction

This protocol has been developed to illustrate the types of laboratory testing to be undertaken in different situations involving patients with acute, generalized vesicular or pustular rash illness. The protocol is composed of four charts, each illustrating a different set of symptoms or circumstances. It has been designed to correlate with "Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol" (www.bt.cdc.gov/agent/smallpox/diagnosis/riskalgorithm). This is a pre-event algorithm, designed to address testing needs when no poxvirus emergency has been detected or declared. Changes to this algorithm may be required in an event. Any updates to the algorithm will be announced by the Laboratory Response Network.

Chart 1 lists the symptoms associated with acute, generalized vesicular or pustular rash illness and categorizes the risk of smallpox according to the patient's signs and symptoms.

Chart 2 presents a flow chart for laboratory testing of specimens from patients presenting with acute, generalized vesicular or pustular rash illness, following the assessment per the "Acute, Generalized Vesicular or Pustular Rash Illness" protocol (see above and chart 1 for abstraction of the protocol). A two-armed algorithm is presented to reduce the time to receive results and to ensure that testing of high-risk specimens is confined to laboratories with appropriate biosafety levels and expertise. The two arms of the testing algorithm are for 1) specimens from individuals with low- and moderate-risk symptoms and 2) specimens from individuals with high-risk symptoms.

Major points:

a) high-risk specimens/cases require consultation with CDC
b) low- or moderate-risk specimens/cases should be worked-up for more common causes of febrile exanthema. Due to the differences in run temperature between the Non-variola Orthopoxvirus PCR and the Orthopoxvirus PCR, the two assays cannot be performed simultaneously. If orthopoxvirus is suspected, then the Non-variola Orthopoxvirus PCR permits the laboratory to identify an orthopoxvirus and reassure that the specimen does not contain variola. The Orthopoxvirus generic PCR can be performed subsequently to provide additional confidence in the result.
c) in the absence of endemic smallpox disease, the indiscriminate use of variola tests will lead to false positives.

Chart 3 presents a testing algorithm that should be used when a smallpox vaccine adverse event or monkeypox infection is suspected.

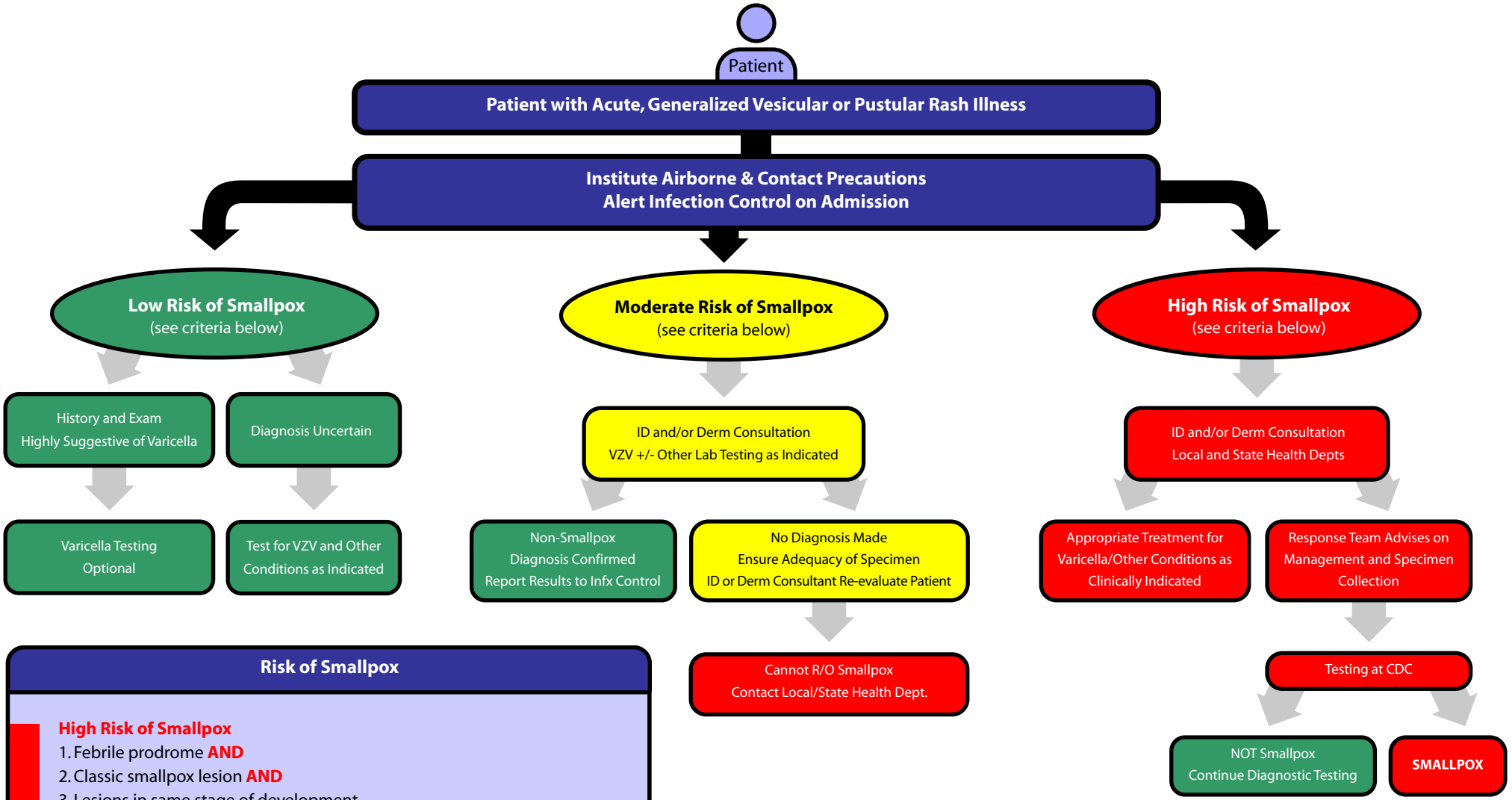
Chart 4 presents an orthopoxvirus testing algorithm for environmental samples.

The testing protocols are supported at Laboratory Response Network (LRN) reference laboratories. Details for performance and interpretation of each assay are specified in each LRN procedure.

Details on specimen collection can be found at the following websites:

Smallpox vaccine: www.bt.cdc.gov/agent/smallpox/vaccination/vaccinia-specimen-collection.asp
Smallpox: www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-d.pdf
Monkeypox: www.cdc.gov/ncidod/monkeypox/diagspecimens.htm

ACUTE, GENERALIZED VESICULAR OR PUSTULAR RASH ILLNESS PROTOCOL



Risk of Smallpox

High Risk of Smallpox
1. Febrile prodrome **AND**
2. Classic smallpox lesion **AND**
3. Lesions in same stage of development

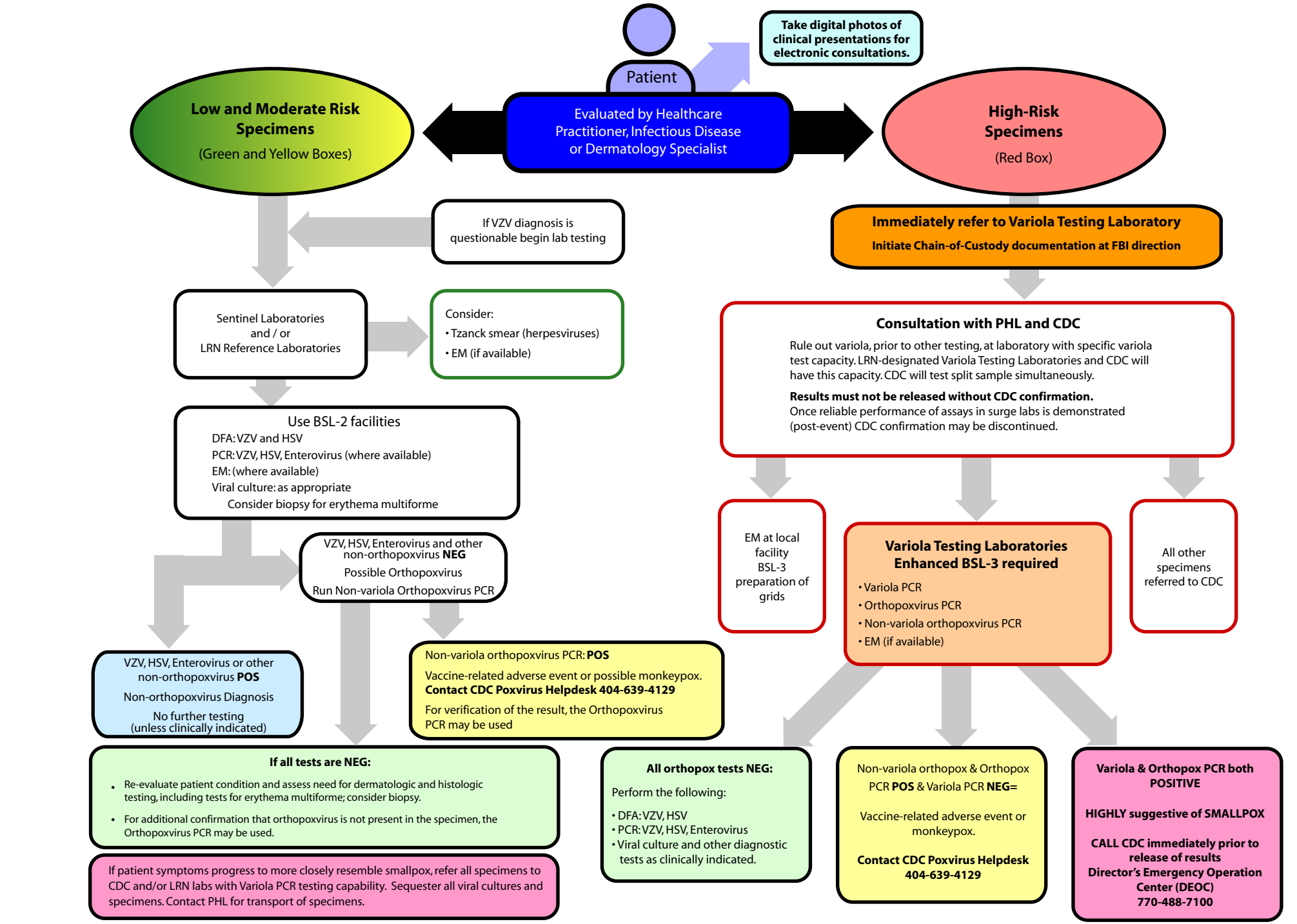
Moderate Risk of Smallpox
Febrile prodrome **AND** one other **MAJOR** smallpox criterion **OR**
Febrile prodrome **AND** **>4 MINOR** smallpox criteria

Low Risk of Smallpox
No febrile prodrome **OR**
Febrile prodrome **AND** **<4 MINOR** smallpox criteria

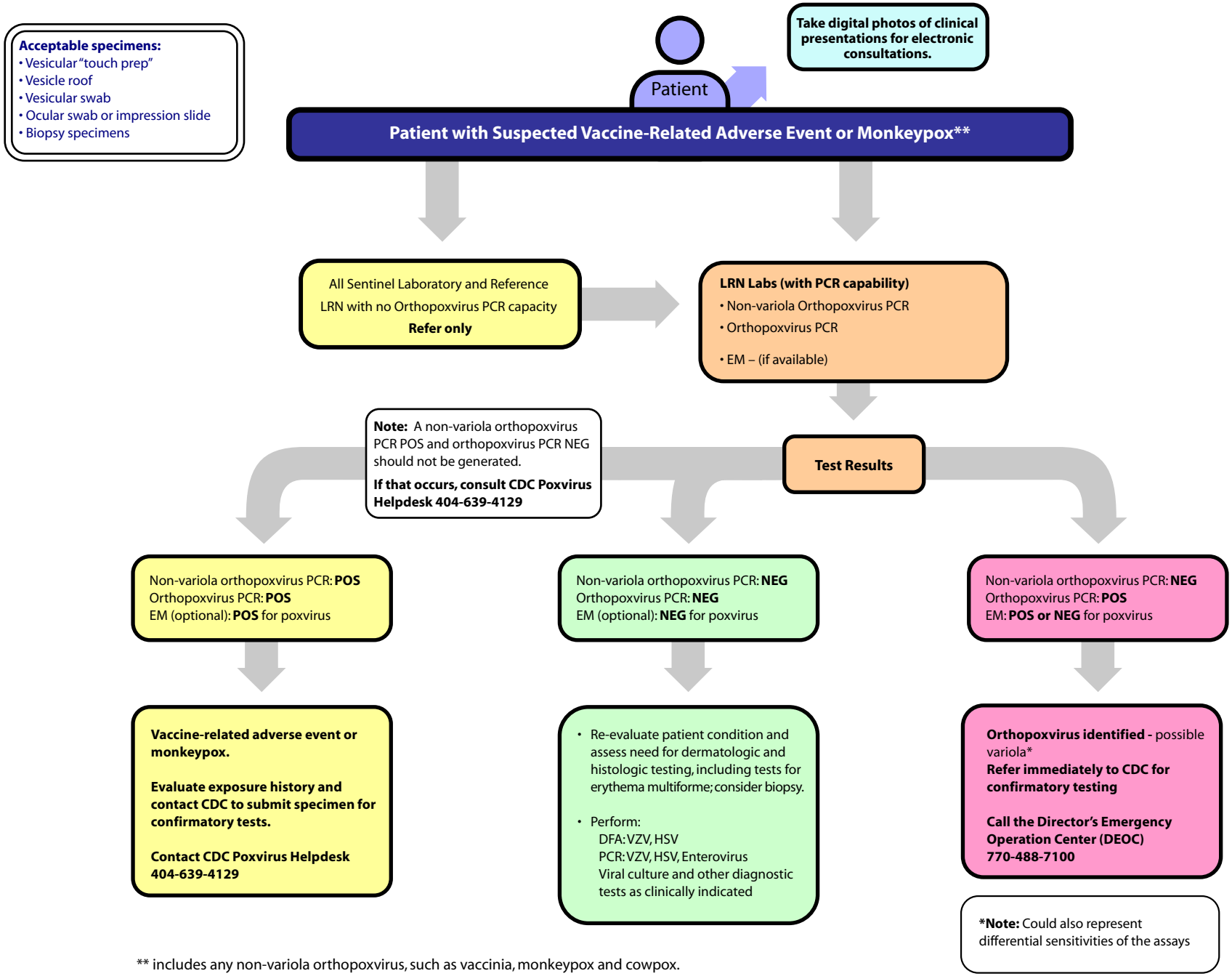
Major Smallpox Criteria:
- Febrile prodrome
  - >101F, 1-4 days prior to rash onset
  - with headache, back ache, or abdominal pain
- Firm, deep-seated, well-circumscribed vesicles/pustules
- Lesions in the same stage of development in any one area of the body

Minor Smallpox Criteria:
- Centrifugal distribution of lesions
- First lesions in the pharynx, oral mucosa
- Patient appears "toxic"
- Slow evolution of rash
  - 1-2 days each stage: macule, papule, vesicle
- Lesions on the palms and soles

LABORATORY TESTING FOR ACUTE, GENERALIZED VESICULAR OR PUSTULAR RASH ILLNESS IN THE UNITED STATES



LABORATORY TESTING FOR SUSPECTED SMALLPOX VACCINE (VACCINIA) ADVERSE EVENTS OR MONKEYPOX IN THE UNITED STATES



** includes any non-variola orthopoxvirus, such as vaccinia, monkeypox and cowpox.

LABORATORY TESTING FOR ENVIRONMENTAL SAMPLES IN THE UNITED STATES