# Initial Competency Assessment: Smallpox Vaccine Reconstitution

**Clinic:**

**Employee Name:** ________________  **Assessment Start Date:** ________________  **Completion Date:** ________________

<table>
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<tr>
<th>Required Competency or Skill</th>
<th>* Self Assessment</th>
<th>Orientation (Preceptor initials &amp; date)</th>
<th>+ Eval Method</th>
<th>Competency Validated by Supervisor (Signature &amp; date)</th>
<th>Comments/Additional Resources</th>
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<tbody>
<tr>
<td><strong>Smallpox Vaccine Reconstitution</strong></td>
<td><strong>CRITICAL THINKING:</strong> Understands clinical guidelines and demonstrates clinical proficiency in appropriate administration, documentation and patient teaching for the smallpox vaccine. Explains procedures in an age-appropriate manner according to the level of understanding of the patient and the family. Approaches patient in professional and non-threatening manner.</td>
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1. Ensures vaccine has been kept in the refrigerator and that refrigeration temperature has been maintained between 2-8˚C or 36-46˚ F.

2. Obtains smallpox vaccine and gathers supplies for reconstitution. (lyophilized vaccine, diluent, 5/8”-25G needle, 1 cc syringe, gloves). Goggles or face shield optional.

3. Inspects diluent vials for discoloration or particulate matter. (contacts manufacturer if concerned about color or particulate matter)

4. Checks expiration date of vaccine and diluent vials. **CRITICAL THINKING:** When removed from freezers in the Strategic National Stockpile and shipped to local clinics at refrigerator temperatures, ACAM2000™ vaccine bulk packages are distributed with 17 month expiration to be completed at local clinic placed on vial. Diluent vials are marked only with a manufacture date. Diluent expires 5 years from manufacture date.

5. Washes hands and dons gloves (also dons face shield or goggles, if desired).

6. Removes flip cap seals on vaccine and diluent vials. ACAM2000™ Package Insert

7. Wipes off vial stoppers with alcohol pads and allows to dry. ACAM2000™ Package Insert

8. Peels open and removes the 1mL syringe and needle from the package. ACAM2000™ Package Insert

9. Aseptically removes plastic cap from needle end of the syringe. ACAM2000™ Package Insert

10. Carefully inserts and withdraws only 0.3mLs diluent from diluent vial. ACAM2000™ Package Insert

11. Aseptically inserts the needle through the rubber stopper of the vaccine (cont.) ACAM2000™ Package Insert

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*Self Assessment + Evaluation/Validation Methodologies

1 = Experience  
2 = Needs Practice/Assistance  
3 = Never Done  
NA = Not Applicable

T = Tests  
D = Demonstration/Observation  
V = Verbal  
I = Interactive Class
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11. (cont.) vial up to the first hub.

12. Depresses the plunger, ensuring that the full 0.3mLs of diluent is delivered into the vial.

13. Withdraws diluent needle and syringe and discards in biohazard waste container.

14. If necessary, swirls vial gently to allow complete reconstitution.

15. Records date of reconstitution on vaccine vial label.

16. Inspects vaccine vial for discoloration or particulate matter. (Contact manufacturer if discolored or particulate matter noted).

17. Stores reconstituted vaccine at 2˚ to 8˚ C (36˚ to 46˚ F) when not in actual use. The properly stored vaccine may be administered for up to 30 days after reconstitution.

**CRITICAL THINKING:** Reconstituted vaccine should be a clear to slightly hazy, colorless to straw-colored liquid free from extraneous matter.

**CRITICAL THINKING:** Exposure of reconstituted vaccine to room temperature during vaccination sessions should be minimized by placing it in manufacturer suggested temperatures (2˚ to 8˚ C /36˚ to 46˚ F) in between patient administration.

Preceptor’s Initials: __________________________ Printed Name: __________________________ Signature: __________________________

Preceptor’s Initials: __________________________ Printed Name: __________________________ Signature: __________________________

I understand the topics listed, I will be allowed to perform only those tasks listed for my skill level/scope of practice and only after I have successfully demonstrated competency in those tasks.

Employee Signature: __________________________ Date: __________________________ Signature of Supervisor: __________________________ Date: __________________________

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*Self Assessment: 1 = Experienced, 2 = Needs Practice/ Assistance, 3 = Never Done, NA = Not Applicable
+ Evaluation/Validation Methodologies: T = Tests, D = Demonstration/Observation, V = Verbal, I = Interactive Class