

Methodist Health Services Corporation & UnityPoint Health Methodist  Laboratory  CELL PROCESSING	Page # 1 of 2	Section: UPM CP	Policy #: CP:022/01
	Approved by: see signature block at end of document		Date: 5/24/04
	Date Revised: 5/24/04, 9/4/09, 4/10, 6/26/12, 7/11/16, 4/19/17		
	Date Reviewed:		
	Policy/Revision Submitted by: Deb Rinne (Adapted from Mike Stinson)		
	JCAHO Standard: NA		
Policy Guideline On: <b>Validation Protocol Policy</b>			

**I. POLICY STATEMENT**

Protocols shall be developed, implemented, and documented for the validation of significant components of facilities, processes, equipment, regents, labels, containers, packaging materials, and computer systems.

**II. PURPOSE:**

Validation establishes documented evidence that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

**III. EQUIPMENT:**

Validation Protocol Form

**IV. POLICY SCOPE:**

All personnel involved in the Cell Processing Laboratory.

**V. GENERAL INFORMATION:**

- A. Determination of which program elements are to be validated shall be made by the Cell Processing Laboratory Director.
- B. Validation may be prospective or retrospective
- C. The Validation Protocol should include the purpose, system (or process/equipment) description, study plan, study procedure, acceptance criteria, results, conclusions, recommendations, approval signatures, references, and any attachments.

**VI. PROCEDURE:**

- A. Obtain and complete a "Validation Protocol Form" (CP:056)
- B. At the completion of the Validation study, the documented results will be reviewed by the Cell Processing Laboratory Director.

**VII. DISTRIBUTION**

A hard copy of this procedure is located in the Cell Processing manual at the Cell Processing bench

<b>MEDICAL DIRECTOR</b>		
DATE	NAME	SIGNATURE
March 4, 2017	Elizabeth A. Bauer-Marsh, M.D.	<i>Elizabeth A. Bauer-Marsh, MD</i>
<b>SECTION MEDICAL DIRECTOR</b>		
May 13, 2016	Julia Adams, M.D.	<i>Julia Adams, M.D.</i>

<b>REVISION HISTORY (began tracking 2011)</b>			
Rev	Description of Change	Author	Effective Date
1	Added reference to forms #'s	D. Rinne	4/11/14
2	Removed reference to FACT and removed maintenance & storage section	Deb Rinne	01/31/17

**Reviewed by**

Lead	Date	Coordinator/Manager	Date	Medical Director	Date
D. Rinne	4/11/14			<i>D. Rinne MD</i>	3/14
D. Rinne	3/3/16	<i>Kathryn L. Turpin</i>	5/30/16	<i>Julia Adams, M.D.</i>	7/11/16
D. Rinne	1/22/17	<i>Jane Bambersek</i>	2/3/17	<i>Julia Adams, M.D.</i>	4/19/17