



MTN 008 (180)

PKM-1 (061)

Visit Code .

1

Participant ID

- - - 0
Site Number Participant Number Chk Who

Maternal Pharmacokinetics

Specimen Collection Date

/ /
dd MMM yy

- 1. Participant height: cm
- 2. Participant weight: kg

MATERNAL BLOOD COLLECTION AND GEL ADMINISTRATION—PREGNANCY AND LACTATION COHORTS

Not done/ Not collected serum PBMC 24-hour clock hr min

<input type="checkbox"/>	3. Pre-gel blood draw	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	4. Gel administration.....			<input type="text"/>	:	<input type="text"/>	<input type="text"/>
		serum	PBMC	hr		min	
<input type="checkbox"/>	5. 1-hour post-gel blood draw.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	6. 2-hour post-gel blood draw.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	7. 4-hour post-gel blood draw.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	8. 6-hour post-gel blood draw.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	9. 8-hour post-gel blood draw.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>

MATERNAL BLOOD COLLECTION—PREGNANCY COHORT

Not done/ Not collected serum PBMC 24-hour clock hr min

<input type="checkbox"/>	10. Blood collection at delivery visit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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MATERNAL BREAST MILK AND GEL ADMINISTRATION—LACTATION COHORT

Not done/ Not collected 24-hour clock hr min

<input type="checkbox"/>	11. Pre-gel milk specimen	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	12. Gel administration.....	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	13. 2-hour post-gel milk specimen	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	14. 4-hour post-gel milk specimen	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	15. 6-hour post-gel milk specimen	<input type="text"/>	:	<input type="text"/>	<input type="text"/>

Comments: _____

Maternal Pharmacokinetics (PKM-1)

Purpose: This form is used to document maternal pharmacokinetics and stored specimen collection as well as study gel administration information.

General Information/Instructions: This form is completed for each maternal study participant, at the Enrollment Visit (Day 0), the Day 6 Visit, and the Delivery Visit (Pregnancy Cohort only).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 1 and 2:** Use leading zeros when needed.
- **Items 3–15:** If any of the specimens/procedures listed in items 3–15 were not collected or performed, mark the “Not done/Not collected” box and specify the reason on the Comments line. For items 3 and 5–10, mark the corresponding box to indicate that serum and/or PBMCs were **stored**. When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).

Note: Item 10 is only completed for mothers in the Pregnancy Cohort. Items 11–15 are only completed for mothers in the Lactation Cohort.