



MTN 008 (180)

PKI-1 (062)

Visit Code   .

1

**Participant ID**

-     -  -  1

Site Number Participant Number Chk Who

**Infant Pharmacokinetics**

**Specimen Collection Date**

dd MMM yy

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

**INFANT BLOOD COLLECTION (PREGNANCY COHORT)**

Not done/  
Not collected

- 3. Delivery Visit cord blood .....
- 4. Delivery Visit blood .....

24-hour clock  
hr min

:

:

**INFANT BLOOD COLLECTION (LACTATION COHORT)**

Not done/  
Not collected

- 5. 6-hour post-gel maternal dosing blood .....

24-hour clock  
hr min

:

Comments: \_\_\_\_\_

14-FEB-11

0  1  
Language

\_\_\_\_\_  
Staff Initials / Date

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## Infant Pharmacokinetics (PKI-1)

**Purpose:** This form is used to document infant pharmacokinetics and stored specimen collection.

**General Information/Instructions:** This form is completed for each infant study participant, at the Enrollment Visit (Day 0) (Lactation Cohort only), the Day 6 Visit (Lactation Cohort only), 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.
- **Item 4:** Infant blood is only collected when cord blood cannot be collected.
- **Items 3–5:** If any of the specimens listed in items 3–5 were not collected, mark the “Not done/Not collected” box and specify the reason on the Comments line. When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).

*Note: Items 3 and 4 are only completed for infants in the Pregnancy Cohort. Item 5 is only completed for infants in the Lactation Cohort.*