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**1.** **Introduction**

PROVIDE\_Study\_Files\_Release1.1 contains additional derived management data pertaining to maternal and infant biomarkers assayed during the course of PROVIDE Study clinical trial in Bangladesh.

This package contains the following:

mgmt\_lab\_biomarkers\_documentation.docx This document

mgmt\_lab\_biomarkers Directory of data files

mgmt\_lab\_biomarkers\_DataDefintion Directory of data definition files

The details of the tables are provided in this document.

**2. Derived Biomarkers**

This release contains 3 flat files with one row per enrolled child (700) derived from individual lab results files; compiled and presented by specimen type such as Infant Blood, Clinical stool in case of Infants. Maternal lab results derived from Breastmilk and Blood are compiled in a single flat file as listed below.

1. **mgmt\_bv\_biomarker\_blood:** derived to include systemic inflammation & nutritional biomarkers, cytokines and vaccine antibodies.
2. **mgmt\_bv\_biomarker\_clinicstool:** include systemic inflammation biomarkers.
3. **mgmt\_bv\_biomarker\_maternal:** includes lab assay results from both maternal blood and breastmilk specimens.

Please note that not all lab results are included in the flat file and if the specimen was not collected for a child or lab results are not available, *the row is left blank for all variables*. And we retained codes such -9 or -9.999 applied for missing data from the original file. In addition, age when sample is drawn or collected is included for each biomarker separately because not all samples at a specific study visit are assayed for all biomarkers.

The following table indicates the lab data files chosen to derived flat files along with file name for clarity.

|  |  |  |  |
| --- | --- | --- | --- |
| **Lab Assay results** | | **Flat file** | **Derived file name** |
| lab\_bv\_abo | Infant Blood Group |  |  |
| **lab\_bv\_act** | **Infant Activin A measure** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_ala** | **Infant Alpha -1- anti trypsin results** | Yes | mgmt\_bv\_biomarker\_clinicstool |
| **lab\_bv\_bml** | **Breast Milk lipid profile** | Yes | mgmt\_bv\_biomarker\_maternal |
| **lab\_bv\_calp** | **Infant Calprotectin results** | Yes | mgmt\_bv\_biomarker\_clinicstool |
| **lab\_bv\_cmv** | **Infant Cytomegalovirus IgG measure results** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_cmvrt** | **Infant CMV-RT PCR results** | Yes | mgmt\_bv\_biomarker\_clinicstool |
| **lab\_bv\_crem\_prkca** | **Infant CREM and PRKCA genotype** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_crp** | **Infant CRP results** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_ctt** | **Infant tetanus measure** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_ctu** | **Infant cytokine assay results** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_cytbm** | **Breast milk Cytokine measure** | Yes | mgmt\_bv\_biomarker\_maternal |
| **lab\_bv\_cytcp** | **Infant Plasma Cytokine measure** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_cytmp** | **Maternal Plasma Cytokine measure** | Yes | mgmt\_bv\_biomarker\_maternal |
| lab\_bv\_dsgene | Diarrheal Stool Rota Gene Expression data |  |  |
| **lab\_bv\_egf** | **Breast milk EGF biomarker measure** | Yes | mgmt\_bv\_biomarker\_maternal |
| **lab\_bv\_endotox** | **Infant Endotoxin results** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_fer** | **Infant Ferritin Measure** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_hla** | **Infant HLA Measure** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_lep** | **Infant Leptin receptor genotype data** | Yes | mgmt\_bv\_biomarker\_blood |
| lab\_bv\_lps | Infant LPS/Endocab measure | Yes | mgmt\_bv\_biomarker\_blood |
| lab\_bv\_lm | Infant Lactulose and Mannitol measure |  |  |
| **lab\_bv\_mfge8** | **Breast Milk MFGE8 biomarker measure** | Yes | mgmt\_bv\_biomarker\_maternal |
| **lab\_bv\_mpo** | **Infant Myeloperoxidase measure** | Yes | mgmt\_bv\_biomarker\_clinicstool |
| **lab\_bv\_neop** | **Infant Neopterin measure** | Yes | mgmt\_bv\_biomarker\_clinicstool |
| lab\_bv\_pals | Infant Polio ALS measure data |  |  |
| lab\_bv\_pcr | Infant diarrheal stool PCR for Rota, Astro, Noro, Sapo viruses. |  |  |
| lab\_bv\_pcrproto | Infant diarrheal stool PCR for protozoa panel. |  |  |
| lab\_bv\_polcul | Infant polio culture |  |  |
| lab\_bv\_polpcr | Infant Polio PCR measure data |  |  |
| lab\_bv\_polsna | Polio Neutralizing Antibody |  |  |
| lab\_bv\_qpcr | Infant Polio QPCR measure |  |  |
| lab\_bv\_rals | Infant Rota ALS measure data |  |  |
| lab\_bv\_rbmiga | Breast milk Rota IgA measure |  |  |
| **lab\_bv\_rbp** | **Infant RBP measure** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_reg1b** | **Infant Reg1b measure** | Yes | mgmt\_bv\_biomarker\_clinicstool |
| lab\_bv\_rotads | Infant Diarrheal stool Rota ELISA results. |  |  |
| lab\_bv\_rotavs | Infant Viral shedding stool Rota ELISA results. |  |  |
| lab\_bv\_rpliga | Infant Rota plasma IgA measure |  |  |
| lab\_bv\_rpligg | Infant Rota plasma IgG measure |  |  |
| **lab\_bv\_rptype** | **Infant Rota P Type and Lewis Secretor results** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_scd14** | **Infant Soluble CD14 measure data** | Yes | mgmt\_bv\_biomarker\_blood |
| lab\_bv\_speclog | Log maintained on specimen collection |  |  |
| **lab\_sspabm** | **Breastmilk Lewis Secretor Status & Phenotyping Assay** | Yes | mgmt\_bv\_biomarker\_maternal |
| lab\_bv\_tac | PCR results on enteropathogens in infant clinic visit stool at wk6 and wk10 visit |  |  |
| lab\_bv\_tacd | PCR results on enteropathogens in infant diarrheal stool samples and stool samples |  |  |
| **lab\_bv\_vac** | **Infant vaccine data** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_vitd** | **Infant Vitamin D measure data** | Yes | mgmt\_bv\_biomarker\_blood |
| **lab\_bv\_zn** | **Infant Zinc measure data** | Yes | mgmt\_bv\_biomarker\_blood |