

March 02, 2009:

Allocation of Matrix Testing for PTM Studies

1) **Standard PTM Study, Option1:** Method Developers are required to evaluate ALL claimed matrices. The Independent lab is required to evaluate approximately 20% of the total number of claimed matrices. See Table 1 for additional details. The same strain/serovar should be used for each of the matrices evaluated at the Independent Laboratory (if artificially contaminating the matrices) that was evaluated at the Method Developer's laboratory.

Number of Claimed Matrices	Number of Matrices To Be Evaluated at Independent Lab
1 - 5	1
6 - 10	2
11 - 15	3
16 - 20	4

2) **Standard PTM study, Option 2:** Method Developers may choose to outsource all of their method comparison evaluations to a contract laboratory. If all of the method comparison testing is coordinated by the Research Institute, then the contract laboratory can be considered as an Independent Laboratory and no additional method comparison testing will be required.

3) **PTM/MicroVal Joint study:** All inclusivity, exclusivity and method comparison evaluations are performed at the Expert (Independent) Laboratory. No additional method comparison testing is required.

4) **Method Modification (Level 2):** Method Developers are required to evaluate a minimum of three (3) matrices. There is no required evaluation at an Independent Lab. for a Level 2 modification.

5) **Method Modification (Level 3):** Method Developers can follow Standard PTM Option 1 or Option 2.

6) **Matrix Extension:** The number of matrices evaluated at the Independent Lab is determined by the total number of matrices the Method Developer is claiming for the particular method (original validation *plus* any new matrices) as per table 1.

Version 4