

## PSA

### Verify Reportable Ranges (Calibration Verification) every 6 months

Verify that the FastPack® IP System is accurate to the limits of the reportable range specified by Qualigen, Inc. by using the FastPack® IP Total PSA Method Verification Kit.

|   |  |
|---|--|
| <p style="text-align: center;"><b>Low</b></p> <p>Target <input data-bbox="311 577 539 634" type="text"/></p>    | <p style="text-align: center;"><i>Write "Low Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here</i></p>  |
| <p style="text-align: center;"><b>Mid</b></p> <p>Range <input data-bbox="300 976 539 1033" type="text"/></p>    | <p style="text-align: center;"><i>Write "Mid Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here</i></p>  |
| <p style="text-align: center;"><b>High</b></p> <p>Target <input data-bbox="311 1417 539 1474" type="text"/></p> | <p style="text-align: center;"><i>Write "High Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here</i></p> |

The Verifier results must be within the following ranges to accept the Manufacturer's Reportable Range:

|                            | Low Verifier | High Verifier |
|----------------------------|--------------|---------------|
| Hybritech Standard         | < 0.04 ng/mL | > 50 ng/mL    |
| WHO International Standard | < 0.04 ng/mL | > 40 ng/mL    |

If either result is different than the above, record the reportable range based on actual observed values. The mid value must be within the range designated on the range card. If it is not, repeat the test. If any value is out of range after repeating the test, contact Qualigen System Support.

- Accept Manufacturer Reportable Range
- DO NOT Accept. Derived Reportable Range: \_\_\_\_\_