

AccuSet™ Syphilis Mixed Titer Performance Panel

0820-0514 / Batch #10690676

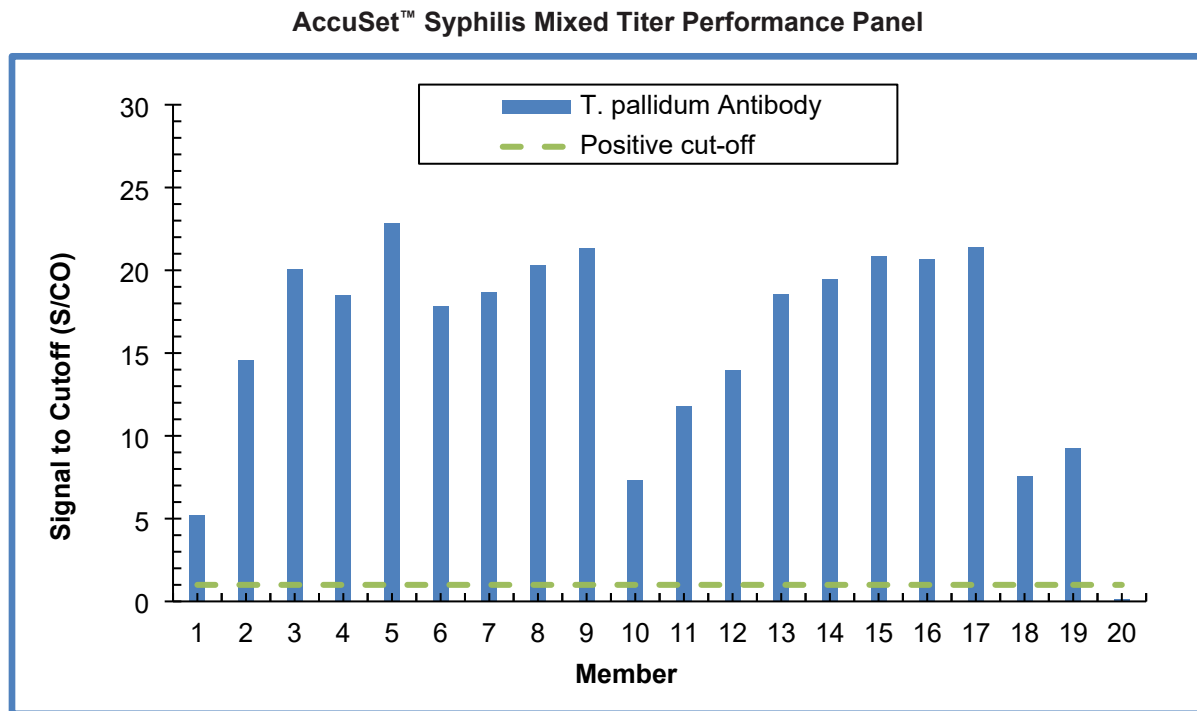
OVERVIEW

AccuSet™ Syphilis Mixed Titer Performance Panel 0820-0514 / Batch #10690676 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to *treponema pallidum*. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available rapid plasma reagin (RPR) and *treponema pallidum* antibody assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity for several RPR and *Treponema pallidum* test methods. One sample is included as a non-reactive sample and is negative for all RPR and *treponema pallidum* test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. LGC SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and found negative for anti-HIV-1/2, anti-HCV, and HBsAg. This does not ensure the absence of these or other human pathogens.



This graph represents panel member reactivity to the Abbott ARCHITECT Syphilis TP test method.

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Panel Member Information

| Panel Member | SeraCare Batch # | SeraCare Donor ID # | Bleed Date |
|--------------|------------------|---------------------|-------------|
| 01 | 10538086 | BD459704 | 29-May-2020 |
| 02 | 10267121 | BD328555 | 06-Aug-2016 |
| 03 | 10267111 | BD328551 | 06-Jan-2017 |
| 04 | 10267060 | BD328525 | 29-Oct-2016 |
| 05 | 10267086 | BD328535 | 28-May-2016 |
| 06 | 10267159 | BD328578 | 06-Sep-2016 |
| 07 | 10267155 | BD328577 | 29-Aug-2016 |
| 08 | 10513221 | BD444932 | 08-Apr-2020 |
| 09 | 10513226 | BD444935 | 26-Apr-2020 |
| 10 | 10267103 | BD328546 | 08-Aug-2016 |
| 11 | 10267124 | BD328556 | 02-Jan-2017 |
| 12 | 10267172 | BD328584 | 20-Jul-2016 |
| 13 | 10267158 | BD328577 | 05-Sep-2016 |
| 14 | 10267186 | BD328594 | 06-Feb-2016 |
| 14 | 10267149 | BD328572 | 23-Jan-2017 |
| 16 | 10267148 | BD328572 | 19-Jan-2017 |
| 17 | 10513234 | BD444938 | 29-Apr-2020 |
| 18 | 10513237 | BD444940 | 26-May-2020 |
| 19 | 10612853 | BD334294 | 26-Feb-2022 |
| 20 | 9252293 | NA | NA |

NA = Not Available

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Treponema pallidum Antibody Assays¹

| Panel Member | Abbott ARCHITECT Syphilis TP (S/CO) | Roche cobas® Elecsys Syphilis (COI) | DiaSorin LIAISON® Treponema Assay (Index Value) |
|---------------|---|---|---|
| 01 | 5.23 | 15.67 | 2.80 |
| 02 | 14.56 | 19.05 | 31.55 |
| 03 | 20.10 | 138.80 | >70.00 |
| 04 | 18.50 | 310.85 | 54.50 |
| 05 | 22.88 | 263.20 | 46.10 |
| 06 | 17.84 | 241.30 | 59.00 |
| 07 | 18.68 | 149.50 | 48.90 |
| 08 | 20.32 | 276.50 | 24.25 |
| 09 | 21.32 | 308.00 | 36.95 |
| 10 | 7.32 | 19.65 | 7.51 |
| 11 | 11.81 | 53.47 | 20.35 |
| 12 | 13.95 | 64.70 | 38.55 |
| 13 | 18.54 | 184.75 | 48.00 |
| 14 | 19.44 | 319.20 | 60.70 |
| 15 | 20.85 | 209.95 | 40.90 |
| 16 | 20.70 | 190.65 | 44.50 |
| 17 | 21.40 | 261.05 | 43.30 |
| 18 | 7.58 | 2.06 | 3.74 |
| 19 | 9.24 | 32.95 | 10.17 |
| 20 | 0.13 | 0.09 | <0.10 |
| Test Date | 22-Jan-2024 | 19-Jan-2024 | 18-Jan-2024 |
| Test Site | LGC | RL | LGC |
| Kit Part Code | 8D06 | NA | 310480 |
| Kit Lot No. | 54395BE00 | 737388 | 113073 |
| Kit Exp. Date | 13-Jul-2024 | 31-Aug-2024 | 24-Nov-2024 |

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.
LGC = LGC SeraCare; RL = Reference Lab; NA = Not Available

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Treponema pallidum IgG/IgM and Rapid Plasma Reagin (RPR) Assays

| Panel Member | DRG Treponema pallidum IgM ELISA (S/CO) ¹ | Trinity Biotech CAPTIA™ Syphilis (T. pallidum)-G (S/CO) ¹ | ASI RPR Card Test ² | BD Macro-Vue™ RPR Card Test ^{2,3} |
|---------------|--|---|-----------------------------------|---|
| 01 | 0.07 | 2.06 | NEG | NEG |
| 02 | 0.23 | 2.40 | POS | 1:8 |
| 03 | 1.51 | 3.77 | POS | 1:16 |
| 04 | 0.36 | 3.11 | POS | NEG |
| 05 | 1.62 | 5.10 | POS | 1:16 |
| 06 | 0.60 | 3.25 | POS | 1:2 |
| 07 | 3.70 | 3.11 | POS | 1:16 |
| 08 | 5.29 | 3.81 | POS | 1:64 |
| 09 | 1.95 | 3.94 | POS | 1:32 |
| 10 | 0.15 | 1.47 | NEG | NEG |
| 11 | 0.12 | 2.12 | NEG | NEG |
| 12 | 0.08 | 2.29 | NEG | NEG |
| 13 | 4.20 | 3.75 | POS | 1:32 |
| 14 | 2.11 | 3.86 | POS | 1:16 |
| 15 | 2.74 | 3.79 | POS | 1:16 |
| 16 | 2.66 | 3.82 | POS | 1:16 |
| 17 | 2.41 | 3.99 | POS | 1:16 |
| 18 | 0.31 | 0.85 | NEG | NEG |
| 19 | 0.23 | 1.43 | NEG | NEG |
| 20 | 0.11 | 0.12 | NEG | NEG |
| Test Date | 26-Feb-2024 | 25-Jan-2024 | 08-Feb-2024 | 24-Jan-2024 04-Mar-2024 |
| Test Site | LGC | LGC | LGC | LGC |
| Kit Part Code | EIA-4267R | 800-970 | 900100 | 274449 |
| Kit Lot No. | 129M/K103 | 800-970-164 | 4A09R3 | 3139569 |
| Kit Exp. Date | 31-Jan-2025 | 28-May-2025 | 31-Oct-2025 | 21-May-2025 |

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

²Results are reported as singlicate testing; positive/reactive results are noted in bold red.

³RPR results are endpoint dilutions.

LGC = LGC SeraCare

The package insert for this panel can be found at
www.seracare.com.

A printed copy of the package insert or data sheet may
be requested by email at CDx-Info@LGCGroup.com or
by phone at 508.244.6400.