



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Remel Inc Recalls Thermo SCIENTIFIC Sensititre Plate Gram Negative IVD AST due to false susceptible results

Recall Date	Product Description	Recalling Firm	Recall Reason
12/14/2022	Thermo SCIENTIFIC Sensititre Plate, GN4F, Gram Negative IVD AST 1917 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre GN6F, Gram Negative IVD AST 2471 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem,

			imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre GN7F, Gram Negative IVD AST 8073 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre HPB1, Gram Negative IVD AST 665 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre CMC5VGNF, Gram Negative IVD AST 588 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results

			for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre CMC7AFLF, Gram Negative IVD AST 1647 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre MDRGN3F, Gram Negative IVD AST 70 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.

12/14/2022	Thermo SCIENTIFIC, Sensititre STP6F, Gram Negative IVD AST 2656 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.
12/14/2022	Thermo SCIENTIFIC, Sensititre STP7F, Gram Negative IVD AST 9 units	Remel Inc, Lenexa, Kansas	An internal technical investigation has confirmed that Thermo Scientific" Gram Negative IVD AST Sensititre Plate may lead to false susceptible results for Proteae Tribe (including Proteus spp., Providencia spp., Morganella Morganii) when tested with doripenem, ertapenem, meropenem, imipenem, cefepime, piperacillin/tazobactam and aztreonam.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Numbers: B2232B, B2197, B2012, B1355, B1181, B1173, B1125A	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2247, B2096, B1445, B1263, B1176, B0503A	US Nationwide Distribution including California	October 2022 and prior

I	Lot Numbers: B2317, B2267, B2251, B2177, B2086, B2037, B2034B, B1476, B1424, B1384, B1286, B1215, B1182, B1104, B1051, B1021	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2206A, B2035A, B1333, B1144A, B0483	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2125, B2115	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2281, B2151A, B2034, B1453	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2311B	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2314, B2174, B2036, B1346, B1183, B1115, B1027	US Nationwide Distribution including California	October 2022 and prior
I	Lot Numbers: B2265A	US Nationwide Distribution including California	October 2022 and prior

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