



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Universal Meditech Recalls Diagnosis And ONTMO Pregnancy & Ovulation Tests

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2023	Diagnosis Hcg Pregnancy Urine Test Strip Format REF 100-12	UNIVERSAL MEDITECH INC. Reedley, California	Universal Meditech was violatively distributing said product
11/1/2023	Diagnosis Hcg Pregnancy Urine Test Cassette Format REF 100-13	UNIVERSAL MEDITECH INC. Reedley, California	Universal Meditech was violatively distributing said product
11/1/2023	Diagnosis Pregnancy Test Midstream REF 100-17	UNIVERSAL MEDITECH INC. Reedley, California	Universal Meditech was violatively distributing said product
11/1/2023	Diagnosis Ovulation Predictor Midstream Product4 REF 200-17	UNIVERSAL MEDITECH INC. Reedley, California	Universal Meditech was violatively distributing said product
11/1/2023	Omtmo One Step Ovulation (Lh) Test Strips REF 200-07	UNIVERSAL MEDITECH INC. Reedley, California	Universal Meditech was violatively distributing said product
4/18/2023	Diagnosis Hcg Pregnancy Serum/Urine Test Cassette Format REF 100-27	UNIVERSAL MEDITECH INC. Reedley, California	Universal Meditech was violatively distributing said product

Recall Class	Product Identification	Distribution	Affected Dates
II	Diagnosis Hcg Pregnancy Urine Test Strip Format Model Number: 100-12 UDI-DI Code: None Lot Numbers: All	5025 Units Nationwide including California	5/22/2023 and prior

	products manufactured after March 2021 to include: hCG-S-2101-01 hCG-S-2111-01-S hCG-S-2112-01		
II	Diagnosus Hcg Pregnancy Urine Test Cassette Format Model Number: 100-13 UDI-DI Code: None Lot Numbers: All products manufactured after March 2021 to include: hCG-M5-2103-01 hCG-M5-2106-02 hCG- M5-2109-01 hCG- M5-2203-01	25000 Units Nationwide including California	5/22/2023 and prior
II	Diagnosus Pregnancy Test Midstream Model Number: 100-17 UDI-DI Code: 710928980000 Lot Numbers: All products manufactured after March 2021 to include: hCG-M11-2103-01 hCG-M11-2105-01	3304 Units Nationwide including California	5/22/2023 and prior
II	Diagnosus Ovulation Predictor Midstream Model Number: 200-17 UDI-DI Code: 697691538914 Lot Numbers: All products manufactured after March 2021 to include: LH-M11-2101-01 LH-M11-2105-01 LH-M11-2106-01 LH-M11-2107-01	3600 Units Nationwide including California	5/22/2023 and prior
II	Omtmo One Step Ovulation (Lh) Test Strips Model Number: 200-07 UDI-DI Code: None Lot Numbers: All products manufactured after March 2021 to include: LH-S-2108-01	40000 Units Nationwide including California	5/22/2023 and prior
II	Diagnosus Hcg Pregnancy Serum/Urine Test Cassette Format Model Number: 100-27 UDI-DI Code: None Lot Numbers: All products manufactured after March 2021 to include: hCG-M5-2106-03	1000 Units Nationwide including California	5/22/2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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