

16.2.8 Listing of Individual Laboratory Measurements by Participant, When Required by Regulatory Authorities

Listing 16.2.8 [Pregnancy Test Results for Subjects with a Positive Pregnancy Test Result
Safety Set](#)

Listing 16.2.8
Pregnancy Test Results for Subjects with a Positive Pregnancy Test Result
Safety Set

Treatment Group: Placebo

Subject ID	Test Performed	Visit	Date of Test (Relative Day)	Result	FSH Sample Collection Date and Time Collected? (Relative Day)
US3172349	URINE	Screening Day 1	2020-08-26 (1)	NEGATIVE	No
	URINE	Day 29	2020-09-23 (29)	POSITIVE	Yes
US3182151					No
	URINE	Screening Day 1	2020-08-04 (1)	NEGATIVE	No
	URINE	Day 29	2020-09-01 (29)	NEGATIVE	Yes
	URINE	Unscheduled	2020-09-29 (29)	POSITIVE	No
US3252009	URINE	Screening Day 1	2020-08-03 (1)	NEGATIVE	No
	URINE	Unscheduled Day 29	2020-09-01 (30)	POSITIVE	Yes 2020-09-01 12:18 (30)
US3372229	URINE	Screening	2020-08-24 (1)	NEGATIVE	No
	URINE	Day 1	2020-08-24 (1)	NEGATIVE	Yes
	URINE	Day 29	2020-09-28 (36)	POSITIVE	No
US3862086	URINE	Screening Day 1	2020-08-28 (1)	NEGATIVE	No
	URINE	Day 29	2020-09-25 (29)	POSITIVE	No

Relative day is defined as days from the most recent injection date.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\1160208.sas 22JUN2021 15:52

Listing 16.2.8
Pregnancy Test Results for Subjects with a Positive Pregnancy Test Result
Safety Set

Treatment Group: mRNA-1273

Subject ID	Test Performed	Visit	Date of Test (Relative Day)	Result	FSH Sample Collection Date and Time Collected? (Relative Day)
US3042177	URINE	Screening	2020-08-13 (1)	NEGATIVE	No
		Day 1			No
	URINE	Day 29	2020-09-10 (29)	NEGATIVE	No
	URINE	Unscheduled	2020-10-22 (43)	POSITIVE	
US3092099	URINE	Screening	2020-08-10 (1)	NEGATIVE	No
	URINE	Day 1	2020-08-10 (1)	NEGATIVE	No
	URINE	Day 29	2020-09-09 (31)	POSITIVE	No
	URINE	Unscheduled	2020-11-05 (88)	POSITIVE	
US3212182	URINE	Screening	2020-08-14 (1)	NEGATIVE	No
		Day 1			No
	URINE	Day 29	2020-09-11 (29)	POSITIVE	No
US3832250	URINE	Screening	2020-08-24 (1)	NEGATIVE	No
		Day 1			No
	URINE	Day 29	2020-09-21 (29)	POSITIVE	Yes 2020-09-21 13:15 (29)

Relative day is defined as days from the most recent injection date.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\1160208.sas 22JUN2021 15:52