

<b>SWEDISH MATCH AB</b>		<b>Subject Number:</b> 123456
<b>Protocol Number:</b> SM 08-01	<b>Investigator:</b> Srinivas	<b>Subject Initials:</b> ____. ____.
<b>Covance Study Number:</b> 7694-105	<b>Site:</b> ABC	

### INFORMATION SESSION

Date of Information Session	Did the subject attend the Information Session?	Comments
22 / 02 / 2023 DD/MMM/YYYY	1 <input checked="" type="checkbox"/> Yes 2 <input type="checkbox"/> No (explain, if No)	

### SUBJECT ELIGIBILITY

<b>Date the Subject Signed the Informed Consent Form:</b> 22 / 02 / 2023 DD/MMM/YYYY				
<b>Did the subject meet all of the inclusion/exclusion criteria?</b> 1 <input type="checkbox"/> Yes 2 <input checked="" type="checkbox"/> No				
<b>If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below.</b>				
Category	Inclusion/Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted DD/MMM/YYYY
1 <input type="checkbox"/> Inclusion 2 <input type="checkbox"/> Exclusion			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____
1 <input type="checkbox"/> Inclusion 2 <input type="checkbox"/> Exclusion			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____
1 <input type="checkbox"/> Inclusion 2 <input type="checkbox"/> Exclusion			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____

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## SCREENING

### DEMOGRAPHICS

Date DD/MMM/YYYY	Date of Birth DD/MMM/YYYY	Gender	Ethnicity
26 / 03 / 2023	14 / 06 / 1988	1 <input checked="" type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input checked="" type="checkbox"/> Hispanic or Latino 2 <input type="checkbox"/> Not Hispanic or Latino
<b>Race</b>			
1 <input checked="" type="checkbox"/> White 2 <input type="checkbox"/> Black or African American 3 <input type="checkbox"/> Asian 4 <input type="checkbox"/> Native Hawaiian or Other Pacific Islander 5 <input type="checkbox"/> American Indian/Alaskan Native 6 <input type="checkbox"/> Other: _____			

### BODY MEASUREMENTS

<b>Were Body Measurements Collected?</b>		<b>Date</b> DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input checked="" type="checkbox"/> No		26 / 03 / 2023
Parameter	Unit	Result
Height	in	165 ____ . ____

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<b>Covance Study Number:</b> 7694-105	<b>Site:</b> _____ABC_____	

## SCREENING

### VITAL SIGNS

<b>Were vital signs collected?</b>	<b>Date</b> DD/MMM/YYYY	<b>Actual Time</b> 24-hour clock	<b>Was Subject seated for 5 minutes?</b>
1 <input type="checkbox"/> Yes 2 <input checked="" type="checkbox"/> No	25 / 03 / 2023	1 0 : 4 5	1 <input checked="" type="checkbox"/> Yes 2 <input type="checkbox"/> No
<b>Parameter</b>	<b>Unit</b>	<b>Result</b>	
Systolic Blood Pressure	mmHg	124 _____	
Diastolic Blood Pressure	mmHg	139/89 _____	
Heart Rate	beats/minute	95 _____	
Respiratory Rate	breaths/minute	18 _____	
Body Temperature	°C	102 _____ . _____	
Weight	lb	85 _____ . _____	

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## SCREENING

### LABORATORY EVALUATIONS

<b>Were the scheduled laboratory samples obtained?</b>		<b>Date</b> DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input checked="" type="checkbox"/> No (Specify samples not done, reason): _____		12 / 12 / 2023
<b>Evaluation:</b> Safety Urine & Blood Tests; Biomarker Blood Tests		
<b>Requisition Number 1:</b> _____		
<b>Requisition Number 2 (if applicable):</b> _____		
<b>Requisition Number 3 (if applicable):</b> _____		
<b>Were there any clinically significant labs?</b> 1 <input type="checkbox"/> Yes (specify below) 2 <input type="checkbox"/> No		
<b>Requisition Number</b>	<b>Test Name</b>	<b>Test Code ID</b>

Note: Attach copy of signed laboratory report.

### URINE PREGNANCY TEST

<b>Result</b>		
1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	9 <input type="checkbox"/> N/A, Male or Woman of Non-childbearing Potential

### URINE DRUG SCREEN

<b>Drug Screen Result*</b>	
1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative

\*If result derived from test performed by a clinical laboratory, attach copy of signed laboratory report to the CRF.