3.2 Medical Requirements Overview

TABLE 3.2: MEDICAL REQUIREMENT OVERVIEW

MRID# and Title	MEDB 2.1 Laboratory Testing
Sponsor	Medical Operations
Discipline	N/A
Category	Medical Requirements (MR)
References	ISS Medical Operations Requirements Document (MORD), SSP 50260 MED Volume B Section 2.1, SSP 50667
Purpose/Objectives	To evaluate crewmember medical fitness for flight and for post-flight recovery by analysis of clinical specimens.
Measurement Parameters	Clinical laboratory examination includes blood for hematology, clinical biochemistry; and urine for routine urinalysis
Deliverables	Preflight and postflight Medical Assessment Testing (MAT) reports to the crew surgeon.
Flight Duration	$\geq$ 30 days
Number of Flights	All flights
Number and Type of Crewmembers Required	All prime and back-up crewmembers for preflight, and prime crewmembers for postflight.
Other Characteristics	Methicillin Resistant Staphylococcus Aureus (MRSA) Screening and Suppression is referenced in MEDB 2.4

3.3 Preflight Training - None 3.4

Preflight Activities

TABLE 3.4: PREFLIGHT ACTIVITIES

<table>
<tr><td>Preflight Activity
Description</td><td colspan="5">Clinical Laboratory Testing will be performed on L-90/30 days and L-20/10 days. The examination will include collection of blood and urine from crewmembers for analyses to enhance the physician’s medical evaluation of crew health prior to flight.

Preflight Clinical Laboratory Testing will include the following: L-90/30 days:
• Blood: Hematology – CBC w/differential, reticulocytes; Chemistry profile – glucose, BUN, creatinine, AST, ALT, GGTP, alkaline phosphatase, total bilirubin, total protein, electrolytes, calcium, magnesium, phosphorus, LDH, uric acid, albumin; Ionized calcium; Thyroid function – free T4, TSH; Iron profile – iron, iron binding capacity, transferrin saturation, ferritin; Special chemistry – C-reactive protein, Serum lipids (total cholesterol, LDL, HDL, Triglycerides)Mouse IgE Allergen Panel; Archive tube.

• Urine: Urinalysis, Urine pregnancy test on females</td></tr>
<tr><td>Schedule</td><td>Duration</td><td>Schedule</td><td>Flexibility</td><td>Blood Volume</td><td>Personnel Required</td></tr>
<tr><td></td><td>Blood Collection - 10 min

Random Urine Collection - 5 min</td><td>L-90/30 days</td><td>Contact lab to assess if schedule accommodations are possible</td><td>30 mL

N/A</td><td>Crewmembers/ Lab Personnel

Self-collected, Lab Personnel</td></tr>
<tr><td>Ground Support Requirements Hardware/Software</td><td>Preflight Hardware:</td><td>Preflight Software:</td><td colspan="3">Test Location:</td></tr>
<tr><td></td><td>Blood Collection supplies & consumables
Urine Collection supplies & consumables
Hematology instrumentation & consumables
Biochemistry instrumentation & consumables
Immunology instrumentation & consumables</td><td>N/A</td><td colspan="3">U.S.
U.S.
U.S.
U.S.
U.S.</td></tr>
</table>

TABLE 3.4: PREFLIGHT ACTIVITIES (cont'd)

Testing Facilities	**Minimum room dimensions:**	**Number of electrical outlets:**	**Temperature requirements:**	**Special lighting:**
	Two rooms, each with dimensions of 10′ x 10′	N/A	Ambient	Sufficient lighting for blood collection & laboratory bench work.
	Hot or cold running water:	**Privacy requirements:**	**Vibration/Acoustic Isolation:**	**Other:**
	Sink with hot and cold water for handwashing.	Private rooms free from distractions. Access to restroom for urine collection.	N/A	Room 1 (Laboratory): Countertops or tables, cabinets, 4 chairs (minimum), refrigerator/freezer, and centrifuge, in a room designated "Laboratory". Room 2 (Blood Collection Area): Gurney (1), table (1), and chairs (2) in a room designated as "Sample Collection Area". Restroom
Constraints/Special Requirements	Mouse IgE Allergen Panel: L-90/30 and the R+3 testing for Mouse IgE Allergen Panel will be sent to the reference laboratory as a paired sample.			
Launch Delay Requirements	Clinical Laboratory analyses will be repeated at the crew surgeon's discretion if launch is delayed.			
Notes	• Upon completion of analyses, any remaining aliquots of all blood samples are archived frozen at the JSC Clinical Laboratory. • Some analyses may be performed in Russia by JSC Clinical Laboratory personnel using equipment hand carried from the U.S.			
Data Delivery	• All hematology, urinalysis and clinical chemistry data will be entered into the Laboratory Information System within 6 hours after laboratory receives samples; data will reside in the crewmembers Electronic Medical Record. Hard copies of the data will be provided to the Crew Surgeon upon request. • Reports from test samples sent to a reference laboratory will be entered into the Laboratory Information System as the results are received in the Clinical Laboratory and will reside in the crewmembers Electronic Medical Record. Copies of the data will be provided to the Crew Surgeon upon request.			

3.5 In-Flight Activities – L+180, see MEDB 1.2 Crew Medical Officer Health Status Evaluations

3.6 Postflight Activities

TABLE 3.6: POSTFLIGHT ACTIVITIES

Postflight Activity — **Description**

Clinical Laboratory Testing will be performed on R+0/1 (landing day), R+3/7 days, and R+14/30 days. The examination will include collection of blood and urine for analyses to enhance the physician's medical evaluation of postflight crew health.

Postflight Clinical Laboratory Testing will include the following:

R+0/1 days:

- Blood: Hematology - CBC w/differential, Archive tube, i-Stat: Na, K, glucose, ionized calcium, pH
- Urine*:* Urinalysis

R+3/7 days: as clinically indicated

- Blood: Hematology - CBC w/differential, reticulocytes; Chemistry profile – glucose, BUN, creatinine, AST, ALT, GGT, alkaline phosphatase, total bilirubin, total protein, electrolytes, calcium, magnesium, phosphorus, LDH, uric acid, albumin; Iron profile – iron, TIBC, % transferrin saturation, ferritin; Special chemistry – C-reactive protein; Thyroid profile – TSH, FT4; IgE Allergen Panel

R+14/30 days:

- Blood: Hematology - CBC w/differential, reticulocytes; Chemistry profile – glucose, BUN, creatinine, AST, ALT, GGTP, alkaline phosphatase, total bilirubin, total protein, electrolytes, calcium, magnesium, phosphorus, LDH, uric acid, albumin; Iron profile - iron, TIBC, % transferrin saturation, ferritin; Special chemistry – C-reactive protein; Lipid profile (total cholesterol, LDL, HDL, Triglycerides); HgbAlC
- Urine: urinalysis

Schedule

Duration	Schedule	Flexibility	Blood Volume	Personnel Required
Blood Collection – 10 min Random Urine Collection – 5 min	R+0/1	Contact Lab	10 mL N/A	Crewmembers (self-collected)/ Lab Personnel
Blood Collection – 10 min	R+3/7 days	Contact Lab	30 mL	Crewmembers/ Lab Personnel
Blood Collection – 10 min Random Urine Collection – 5 min	R+14/30 days	Contact Lab	20 mL N/A	Crewmembers (self-collected)/ Lab Personnel

Table 3.6 Postflight Activities (cont'd)

<table>
<tr><td rowspan="2">Ground Support Requirements Hardware/Software</td><td colspan="2">Postflight Hardware:</td><td>Postflight Software:</td><td>Test Location:</td></tr>
<tr><td colspan="2">Blood Collection supplies & consumables
Urine Collection supplies & consumables
Hematology instrumentation & consumables
Biochemistry instrumentation & consumables
Immunology instrumentation & consumables</td><td>N/A</td><td>U.S. /Russia
U.S. /Russia
U.S.
U.S.
U.S.</td></tr>
<tr><td rowspan="4">Postflight Activity Facilities</td><td>Minimum room dimensions:</td><td>Number of electrical outlets:</td><td>Temperature requirements:</td><td>Special lighting:</td></tr>
<tr><td>Two rooms, each with dimensions of 10′ x 10′</td><td>N/A</td><td>Ambient</td><td>Sufficient lighting for blood collection & laboratory bench work.</td></tr>
<tr><td>Hot or cold running water:</td><td>Privacy requirements:</td><td colspan="2">Other:</td></tr>
<tr><td>Sink with hot and cold water for hand-washing.</td><td>Private rooms free from distractions.
Access to restroom for urine collection.</td><td colspan="2"><u>Room 1 (Laboratory):</u>
Countertops or tables, cabinets, 4 chairs (minimum), refrigerator/freezer, and centrifuge in a room designated "Laboratory".
<u>Room 2 (Blood Collection Area):</u>
Gurney (1), table (1), and chairs (2) in a room designated "Sample Collection Area".
<u>Restroom</u></td></tr>
<tr><td>Constraints/Special Requirements</td><td colspan="4">• R+0 days crewmembers are not required to fast before blood collection.
• Mouse IgE Allergen Panel: L-90/30 and the R+3 testing for Mouse IgE Allergen Panel will be sent to the reference laboratory as a paired sample.</td></tr>
<tr><td>Notes</td><td colspan="4">• Upon completion of analyses, any remaining aliquots of all blood samples are archived frozen in the JSC Clinical Laboratory.

<u>Postflight sample collection outside of U.S.</u>: Sample collection and processing occurring in Russia will require analyses of samples for test that are time critical.
• Some analyses may be performed in Russia by JSC Clinical Laboratory personnel on hand-carried equipment from the U.S.
• Aliquots of blood and urine samples collected by JSC Clinical Laboratory personnel in Russia will be packed in dry ice and hand-carried to the U.S. to be analyzed at JSC.
• The JSC Clinical Laboratory will analyze samples within 6 hours of laboratory receipt of samples from Russia.</td></tr>
</table>

Data Delivery	• All hematology, urinalysis and clinical chemistry data will be entered into the Laboratory Information System within 6 hours after laboratory receives samples; data will reside in the crewmembers Electronic Medical Record. Hard copies of the data will be provided to the Crew Surgeon upon request. • Reports from test samples sent to a reference laboratory will be entered into the Laboratory Information System as the results are received in the Clinical Laboratory and will reside in the crewmembers Electronic Medical Record. Copies of the data will be provided to the Crew Surgeon upon request.

3.7 Summary Schedule

TABLE 3.7: SUMMARY SCHEDULE

ACTIVITY	DURATION OF ACTIVITY	SCHEDULE	FLEXIBILITY	BLOOD VOLUME	PERSONNEL REQUIRED	CONSTRAINTS
Preflight Training – N/A						
Preflight Activity						
Blood Collection	10 min	L-90/30 days	Contact Lab	30 mL	Crewmembers/ Lab Personnel	
Random Urine Collection	5 min			N/A	Crewmembers (self-collected)	
In-flight – L+180, see MEDB 1.2 Crew Medical Officer Health Status Evaluations						
Postflight Activity						
Blood Collection	10 min	R+0/1	Contact Lab	10 mL	Crewmembers/ Lab Personnel	
Random Urine Collection	5 min			N/A	Crewmembers (self-collected)/ Lab Personnel	
Blood Collection	10 min	R+3/7 days	Contact Lab	30 mL	Crewmembers/ Lab Personnel	
Blood Collection	10 min	R+14/30 days	Contact Lab	20 mL	Crewmembers/ Lab Personnel	
Random Urine Collection	5 min			N/A	Crewmembers (self-collected)/ Lab Personnel	