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**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ001, Sex: M, Age (years): 45

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-08-02	162.6 <sup>H</sup>	62.9 <sup>H</sup>	0.78	14.1	6.6	-
Drug A	Visit 1	2024-08-14	89.2 <sup>H</sup>	153.5 <sup>H</sup>	1.12	13.7	6.4	+++
Drug A	Visit 2	2024-08-30	154.3 <sup>H</sup>	110.7 <sup>H</sup>	0.97	13.9	6.8	-
Drug A	Visit 3	2024-09-12	171.4 <sup>H</sup>	116.1 <sup>H</sup>	0.69	NC	5.5	++
Drug A	Visit 4	2024-09-29	203.1 <sup>H</sup>	69.0 <sup>H</sup>	0.37	12.9	6.2	-
Drug A	Visit 5	2024-10-22	231.4 <sup>H</sup>	65.0 <sup>H</sup>	0.54	13.9	6.4	+
Drug A	Visit 6	2024-11-25	82.3 <sup>H</sup>	104.7 <sup>H</sup>	1.91 <sup>H</sup>	11.9 <sup>L</sup>	6.6	-
Drug A	Visit 7	2024-12-22	145.7 <sup>H</sup>	64.9 <sup>H</sup>	0.80	13.5	5.5	-
Drug A	Visit 8	2025-01-16	69.8 <sup>H</sup>	64.4 <sup>H</sup>	0.96	14.1	5.1	-
Drug A	Visit 9	2025-02-16	189.4 <sup>H</sup>	58.3 <sup>H</sup>	0.68	15.3	6.9	+
Drug A	Visit 10	2025-03-16	167.7 <sup>H</sup>	99.8 <sup>H</sup>	1.34 <sup>H</sup>	13.7	5.5	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ002, Sex: F, Age (years): 39

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-01-28	34.7	24.5	0.80	17.4 <sup>H</sup>	6.4	-
Drug A	Visit 1	2024-02-13	17.1	22.0	0.50	12.4	5.6	-
Drug A	Visit 2	2024-02-26	31.5	19.3	0.89	13.4	6.3	+
Drug A	Visit 3	2024-03-10	42.0 <sup>H</sup>	11.9	0.52	13.0	6.8	-
Drug A	Visit 4	2024-03-27	25.6	16.9	1.79 <sup>H</sup>	13.1	5.2	-
Drug A	Visit 5	2024-04-20	10.5	24.7	1.14	16.2	6.3	++
Drug A	Visit 6	2024-05-22	21.8	23.8	0.83	12.9	6.1	-
Drug A	Visit 7	2024-06-14	6.8 <sup>L</sup>	24.3	0.90	15.1	5.8	-
Drug A	Visit 8	2024-07-17	27.3	46.3 <sup>H</sup>	1.03	12.9	6.3	+
Drug A	Visit 9	2024-08-11	36.2	27.6	0.56	13.1	6.9	-
Drug A	Visit 10	2024-09-08	62.8 <sup>H</sup>	22.4	1.17	16.6	6.2	+

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ003, Sex: M, Age (years): 26

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-12-19	14.1	33.7	0.88	14.7	6.5	+++
Drug A	Visit 1	2024-12-30	33.9	17.3	0.60	14.3	6.3	-
Drug A	Visit 2	2025-01-15	20.8	14.3	1.02	13.8	6.1	-
Drug A	Visit 3	2025-01-27	22.5	24.4	0.89	14.0	5.9	-
Drug A	Visit 4	2025-02-11	24.6	31.3	0.53	14.3	5.9	-
Drug A	Visit 5	2025-03-15	28.0	35.8	0.88	14.3	6.2	++
Drug A	Visit 6	2025-04-11	26.1	36.0	1.17	14.7	6.0	++
Drug A	Visit 7	2025-05-06	19.5	21.7	0.63	14.6	6.2	-
Drug A	Visit 8	2025-06-05	19.3	15.4	0.68	14.8	6.0	-
Drug A	Visit 9	2025-07-04	39.9	16.1	1.07	14.5	6.7	+
Drug A	Visit 10	2025-07-31	49.1 <sup>H</sup>	25.2	1.06	12.2	5.7	++

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ004, Sex: F, Age (years): 22

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-04-10	25.3	21.5	0.66	13.8	7.2	-
Placebo	Visit 1	2024-04-25	53.1 <sup>H</sup>	30.1	0.39	15.1	6.3	+
Placebo	Visit 2	2024-05-11	29.2	22.2	0.66	13.6	6.4	-
Placebo	Visit 3	2024-05-19	21.2	39.1	0.73	11.3 <sup>L</sup>	5.1	-
Placebo	Visit 4	2024-06-06	44.2 <sup>H</sup>	29.8	1.11	11.5 <sup>L</sup>	6.1	-
Placebo	Visit 5	2024-07-06	16.1	17.3	0.97	14.6	NC	-
Placebo	Visit 6	2024-08-02	29.7	35.2	0.69	12.7	5.6	-
Placebo	Visit 7	2024-08-25	23.3	37.7	1.00	15.0	6.1	-
Placebo	Visit 8	2024-09-23	24.1	21.9	0.68	11.9 <sup>L</sup>	5.6	-
Placebo	Visit 9	2024-10-26	33.0	26.1	1.29 <sup>H</sup>	14.1	6.1	-
Placebo	Visit 10	2024-11-20	13.4	24.7	0.49	13.8	5.7	+

H, L - Value Outside Normal Ranges  
NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ005, Sex: F, Age (years): 55

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-10-22	31.1	25.5	0.64	11.1 <sup>L</sup>	5.7	+
Placebo	Visit 1	2024-11-07	36.5	24.9	0.83	13.6	6.6	-
Placebo	Visit 2	2024-11-18	30.4	26.0	0.85	17.2 <sup>H</sup>	5.5	+
Placebo	Visit 3	2024-12-01	26.8	13.1	0.39	16.9	5.8	+
Placebo	Visit 4	2024-12-18	28.5	23.9	1.66 <sup>H</sup>	14.9	5.9	++
Placebo	Visit 5	2025-01-13	24.9	22.5	0.75	13.8	5.8	+
Placebo	Visit 6	2025-02-08	NC	NC	NC	NC	NC	NC
Placebo	Visit 7	2025-03-12	32.8	24.3	0.51	15.5	5.4	-
Placebo	Visit 8	2025-04-11	12.0	30.1	0.71	14.2	5.7	-
Placebo	Visit 9	2025-05-07	17.0	22.2	0.81	16.0	5.7	-
Placebo	Visit 10	2025-06-05	65.9 <sup>H</sup>	32.8	0.91	17.6 <sup>H</sup>	6.4	-

H, L - Value Outside Normal Ranges  
NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ006, Sex: M, Age (years): 33

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-11-18	23.5	16.1	0.73	17.6 <sup>H</sup>	5.4	-
Drug A	Visit 1	2024-12-04	13.1	14.1	1.03	16.2	6.2	-
Drug A	Visit 2	2024-12-19	44.9 <sup>H</sup>	42.9 <sup>H</sup>	0.92	14.4	5.9	NC
Drug A	Visit 3	2025-01-02	35.3	34.5	0.88	14.7	6.3	-
Drug A	Visit 4	2025-01-12	18.5	15.9	0.57	16.0	6.4	-
Drug A	Visit 5	2025-02-12	33.9	26.4	0.41	13.4	6.4	+
Drug A	Visit 6	2025-03-12	22.2	24.5	0.66	14.1	6.1	-
Drug A	Visit 7	2025-04-06	22.2	NC	1.74 <sup>H</sup>	13.3	6.1	-
Drug A	Visit 8	2025-05-07	26.5	14.9	0.66	15.3	6.1	-
Drug A	Visit 9	2025-06-02	40.4 <sup>H</sup>	38.1	0.90	16.0	6.0	++
Drug A	Visit 10	2025-06-29	11.5	22.5	0.91	13.4	6.3	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ007, Sex: F, Age (years): 21

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-11-23	27.0	43.3 <sup>H</sup>	1.10	16.1	7.3	++
Placebo	Visit 1	2024-12-08	68.5 <sup>H</sup>	18.4	0.87	16.5	5.6	-
Placebo	Visit 2	2024-12-21	18.6	22.4	0.78	14.8	5.7	-
Placebo	Visit 3	2025-01-07	30.3	22.5	0.84	11.1 <sup>L</sup>	6.6	-
Placebo	Visit 4	2025-01-16	26.4	17.3	0.63	13.8	5.3	+
Placebo	Visit 5	2025-02-18	32.3	38.3	1.04	17.3 <sup>H</sup>	6.6	+
Placebo	Visit 6	2025-03-16	71.8 <sup>H</sup>	14.4	0.50	11.6 <sup>L</sup>	6.6	+++
Placebo	Visit 7	2025-04-14	15.9	17.5	0.34	12.3	5.8	-
Placebo	Visit 8	2025-05-13	20.6	35.8	0.77	14.3	6.0	-
Placebo	Visit 9	2025-06-07	34.7	22.7	0.74	16.0	5.7	-
Placebo	Visit 10	2025-07-04	26.2	16.5	0.39	12.2	7.1	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ008, Sex: F, Age (years): 31

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-05-26	83.4 <sup>H</sup>	70.1 <sup>H</sup>	1.19	15.0	5.7	-
Drug A	Visit 1	2024-06-08	153.0 <sup>H</sup>	157.7 <sup>H</sup>	1.23 <sup>H</sup>	15.9	5.7	-
Drug A	Visit 2	2024-06-25	234.9 <sup>H</sup>	70.7 <sup>H</sup>	0.54	13.1	7.1	-
Drug A	Visit 3	2024-07-08	162.1 <sup>H</sup>	67.3 <sup>H</sup>	0.44	12.6	6.2	+
Drug A	Visit 4	2024-07-20	220.6 <sup>H</sup>	70.1 <sup>H</sup>	1.14	11.4 <sup>L</sup>	4.6	++
Drug A	Visit 5	2024-08-18	113.9 <sup>H</sup>	85.6 <sup>H</sup>	0.73	13.7	6.1	+++
Drug A	Visit 6	2024-09-13	109.8 <sup>H</sup>	157.0 <sup>H</sup>	0.82	15.3	6.2	+
Drug A	Visit 7	2024-10-15	235.8 <sup>H</sup>	101.8 <sup>H</sup>	0.85	15.0	5.5	-
Drug A	Visit 8	2024-11-12	170.5 <sup>H</sup>	151.0 <sup>H</sup>	1.09	12.8	6.0	+
Drug A	Visit 9	2024-12-11	141.2 <sup>H</sup>	130.1 <sup>H</sup>	0.86	13.9	5.6	+++
Drug A	Visit 10	2025-01-02	164.4 <sup>H</sup>	129.8 <sup>H</sup>	1.00	14.4	6.0	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ009, Sex: F, Age (years): 73

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-07-07	14.0	11.1	0.65	15.7	5.4	-
Drug A	Visit 1	2024-07-23	15.2	50.2 <sup>H</sup>	0.98	11.9 <sup>L</sup>	5.8	+++
Drug A	Visit 2	2024-08-05	19.4	22.2	1.19	14.4	5.6	-
Drug A	Visit 3	2024-08-18	25.5	20.0	0.67	14.6	5.7	-
Drug A	Visit 4	2024-08-31	24.2	48.8 <sup>H</sup>	0.60	13.1	5.4	-
Drug A	Visit 5	2024-09-28	26.5	25.8	0.99	14.2	5.3	-
Drug A	Visit 6	2024-10-29	13.2	21.4	0.79	13.1	6.3	-
Drug A	Visit 7	2024-11-22	25.2	12.3	0.78	12.6	6.5	-
Drug A	Visit 8	2024-12-25	22.2	37.6	0.94	12.4	5.9	-
Drug A	Visit 9	2025-01-20	NC	20.7	1.54 <sup>H</sup>	13.8	5.3	-
Drug A	Visit 10	2025-02-13	21.1	21.1	0.89	12.1	5.1	++

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ010, Sex: M, Age (years): 79

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-07-14	47.1 <sup>H</sup>	21.1	0.82	15.6	5.5	-
Drug A	Visit 1	2024-07-28	24.5	43.3 <sup>H</sup>	0.65	11.7 <sup>L</sup>	6.5	-
Drug A	Visit 2	2024-08-14	15.1	54.5 <sup>H</sup>	1.43 <sup>H</sup>	14.4	6.0	-
Drug A	Visit 3	2024-08-25	19.9	34.8	0.75	10.6 <sup>L</sup>	5.2	++
Drug A	Visit 4	2024-09-11	14.9	21.6	0.57	13.2	6.2	+
Drug A	Visit 5	2024-10-09	18.2	13.4	1.64 <sup>H</sup>	14.5	5.8	-
Drug A	Visit 6	2024-11-03	25.5	17.7	1.03	12.4	5.6	-
Drug A	Visit 7	2024-11-29	26.3	27.1	0.97	16.0	6.9	-
Drug A	Visit 8	2024-12-26	13.4	22.8	0.69	11.6 <sup>L</sup>	6.3	-
Drug A	Visit 9	2025-01-28	36.6	16.2	0.88	14.1	6.1	-
Drug A	Visit 10	2025-02-22	21.4	23.4	0.55	11.9 <sup>L</sup>	5.5	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ011, Sex: M, Age (years): 21

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-03-24	127.5 <sup>H</sup>	72.4 <sup>H</sup>	0.56	15.3	6.4	-
Drug A	Visit 1	2024-04-07	55.8 <sup>H</sup>	77.4 <sup>H</sup>	1.33 <sup>H</sup>	14.1	5.7	++
Drug A	Visit 2	2024-04-24	105.1 <sup>H</sup>	126.0 <sup>H</sup>	1.62 <sup>H</sup>	14.6	6.2	-
Drug A	Visit 3	2024-05-07	108.4 <sup>H</sup>	87.3 <sup>H</sup>	0.66	13.3	6.8	++
Drug A	Visit 4	2024-05-20	113.8 <sup>H</sup>	133.5 <sup>H</sup>	1.39 <sup>H</sup>	15.6	6.9	-
Drug A	Visit 5	2024-06-13	141.9 <sup>H</sup>	69.7 <sup>H</sup>	0.53	14.3	6.3	-
Drug A	Visit 6	2024-07-16	92.3 <sup>H</sup>	67.6 <sup>H</sup>	0.74	15.8	6.1	+
Drug A	Visit 7	2024-08-14	150.3 <sup>H</sup>	101.9 <sup>H</sup>	0.69	12.4	5.2	-
Drug A	Visit 8	2024-09-07	107.2 <sup>H</sup>	85.4 <sup>H</sup>	0.63	14.7	5.5	-
Drug A	Visit 9	2024-10-03	195.8 <sup>H</sup>	112.0 <sup>H</sup>	1.28 <sup>H</sup>	14.7	6.5	-
Drug A	Visit 10	2024-11-02	51.2 <sup>H</sup>	88.7 <sup>H</sup>	0.74	13.7	6.3	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ012, Sex: M, Age (years): 21

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-03-23	20.8	27.9	0.61	15.4	5.7	+
Placebo	Visit 1	2024-04-03	31.4	22.9	0.93	14.2	5.4	-
Placebo	Visit 2	2024-04-20	27.3	21.0	1.09	14.3	4.9	-
Placebo	Visit 3	2024-05-03	36.2	43.1 <sup>H</sup>	0.97	14.0	6.0	-
Placebo	Visit 4	2024-05-21	26.2	9.7 <sup>L</sup>	1.48 <sup>H</sup>	15.6	6.8	-
Placebo	Visit 5	2024-06-18	21.8	25.0	1.28 <sup>H</sup>	16.1	5.7	+++
Placebo	Visit 6	2024-07-11	25.6	17.4	0.58	14.5	5.5	-
Placebo	Visit 7	2024-08-13	19.6	13.5	1.85 <sup>H</sup>	10.2 <sup>L</sup>	6.6	-
Placebo	Visit 8	2024-09-06	13.6	13.5	0.77	14.3	5.6	-
Placebo	Visit 9	2024-10-06	24.2	24.6	0.87	14.0	6.1	-
Placebo	Visit 10	2024-11-01	15.1	28.9	1.64 <sup>H</sup>	12.2	5.9	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ013, Sex: M, Age (years): 38

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-09-06	28.9	31.2	0.65	15.6	5.8	-
Drug A	Visit 1	2024-09-20	34.7	11.5	0.98	15.0	6.3	++
Drug A	Visit 2	2024-10-07	32.8	21.9	0.75	17.0	6.3	+
Drug A	Visit 3	2024-10-20	17.1	15.6	0.46	15.9	5.7	-
Drug A	Visit 4	2024-10-31	18.2	19.4	0.74	14.4	5.3	-
Drug A	Visit 5	2024-11-28	36.0	29.7	0.70	12.2	6.1	-
Drug A	Visit 6	2024-12-29	26.3	25.3	0.76	14.7	4.8	+++
Drug A	Visit 7	2025-01-25	14.2	27.0	0.76	12.4	6.1	-
Drug A	Visit 8	2025-02-24	37.4	13.3	0.74	14.1	6.9	++
Drug A	Visit 9	2025-03-20	48.8 <sup>H</sup>	18.1	0.49	12.0	5.7	-
Drug A	Visit 10	2025-04-15	7.2 <sup>L</sup>	47.1 <sup>H</sup>	1.05	13.3	6.5	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ014, Sex: F, Age (years): 57

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-12-17	63.2 <sup>H</sup>	19.2	0.50	NC	5.8	-
Placebo	Visit 1	2024-12-31	54.4 <sup>H</sup>	17.2	0.58	11.8 <sup>L</sup>	6.4	-
Placebo	Visit 2	2025-01-14	33.3	22.8	0.77	11.0 <sup>L</sup>	5.0	-
Placebo	Visit 3	2025-01-25	16.3	31.2	0.57	16.5	5.7	+++
Placebo	Visit 4	2025-02-11	25.5	18.5	1.78 <sup>H</sup>	13.4	5.6	-
Placebo	Visit 5	2025-03-11	38.0	19.5	0.78	13.5	5.7	-
Placebo	Visit 6	2025-04-08	36.9	28.3	1.52 <sup>H</sup>	14.5	6.5	-
Placebo	Visit 7	2025-05-06	14.1	26.2	0.81	13.2	6.3	-
Placebo	Visit 8	2025-06-02	11.0	21.7	1.23 <sup>H</sup>	15.0	6.5	-
Placebo	Visit 9	2025-07-03	35.2	27.0	0.53	12.7	6.2	-
Placebo	Visit 10	2025-07-31	23.9	35.9	0.51	15.9	6.5	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ015, Sex: M, Age (years): 73

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-01-17	29.4	14.2	0.40	13.6	6.5	-
Placebo	Visit 1	2024-01-28	38.9	21.1	0.73	13.6	7.1	+
Placebo	Visit 2	2024-02-15	13.4	24.1	0.72	14.8	6.2	-
Placebo	Visit 3	2024-02-26	NC	NC	NC	NC	NC	NC
Placebo	Visit 4	2024-03-12	18.7	13.1	1.56 <sup>H</sup>	13.8	6.5	-
Placebo	Visit 5	2024-04-10	30.7	45.1 <sup>H</sup>	0.66	12.3	6.3	-
Placebo	Visit 6	2024-05-06	23.9	35.0	0.94	13.0	6.7	-
Placebo	Visit 7	2024-06-05	15.8	24.9	1.19	16.8	5.8	+
Placebo	Visit 8	2024-07-06	23.5	10.3	0.36	12.0	5.8	+
Placebo	Visit 9	2024-07-28	6.9 <sup>L</sup>	32.4	0.57	12.4	6.4	-
Placebo	Visit 10	2024-08-30	17.9	47.1 <sup>H</sup>	0.83	17.0	7.1	-

H, L - Value Outside Normal Ranges  
NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ016, Sex: F, Age (years): 84

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-10-07	47.2 <sup>H</sup>	25.9	1.05	14.2	6.0	+
Placebo	Visit 1	2024-10-18	14.4	28.0	0.52	14.5	6.4	-
Placebo	Visit 2	2024-11-04	15.0	18.3	0.73	14.8	5.1	-
Placebo	Visit 3	2024-11-21	32.9	15.5	1.33 <sup>H</sup>	16.2	5.3	-
Placebo	Visit 4	2024-12-04	18.7	59.7 <sup>H</sup>	0.78	15.0	6.0	-
Placebo	Visit 5	2024-12-29	47.5 <sup>H</sup>	21.7	0.67	13.0	6.7	-
Placebo	Visit 6	2025-01-28	26.2	26.6	0.88	14.0	6.2	+
Placebo	Visit 7	2025-02-23	13.4	23.7	1.02	15.2	6.3	-
Placebo	Visit 8	2025-03-25	30.7	12.3	0.57	14.8	5.4	-
Placebo	Visit 9	2025-04-24	20.6	19.4	0.77	13.0	6.1	-
Placebo	Visit 10	2025-05-17	27.5	13.3	1.47 <sup>H</sup>	12.9	6.1	+

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ017, Sex: M, Age (years): 22

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-06-11	46.3 <sup>H</sup>	12.4	0.92	12.7	6.4	-
Drug A	Visit 1	2024-06-28	34.4	23.6	0.78	11.5 <sup>L</sup>	6.0	-
Drug A	Visit 2	2024-07-07	15.0	23.8	0.79	12.9	5.7	-
Drug A	Visit 3	2024-07-22	11.7	26.9	0.76	13.3	5.8	-
Drug A	Visit 4	2024-08-05	22.8	32.6	0.60	15.2	6.2	-
Drug A	Visit 5	2024-09-03	22.8	24.1	0.53	14.7	5.6	-
Drug A	Visit 6	2024-10-04	43.1 <sup>H</sup>	50.6 <sup>H</sup>	1.16	13.7	6.1	-
Drug A	Visit 7	2024-10-31	24.5	44.2 <sup>H</sup>	0.85	16.4	6.2	-
Drug A	Visit 8	2024-11-28	12.6	50.4 <sup>H</sup>	0.99	12.0	4.6	-
Drug A	Visit 9	2024-12-22	12.8	20.4	0.77	15.9	6.4	-
Drug A	Visit 10	2025-01-18	17.1	17.3	0.81	13.3	6.0	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ018, Sex: M, Age (years): 83

Treatment	Visit	Date						
			ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-12-22	20.8	29.7	0.60	17.3 <sup>H</sup>	6.0	-
Drug A	Visit 1	2025-01-07	23.8	23.5	1.29 <sup>H</sup>	14.3	6.1	-
Drug A	Visit 2	2025-01-18	18.3	17.4	0.40	14.1	6.0	-
Drug A	Visit 3	2025-02-04	35.6	22.8	0.56	15.7	6.6	+
Drug A	Visit 4	2025-02-13	31.2	12.4	0.63	16.6	6.4	-
Drug A	Visit 5	2025-03-19	14.4	22.0	0.84	15.3	5.4	-
Drug A	Visit 6	2025-04-16	26.1	27.5	1.50 <sup>H</sup>	13.0	6.2	+
Drug A	Visit 7	2025-05-13	56.5 <sup>H</sup>	26.3	0.75	12.0	6.9	-
Drug A	Visit 8	2025-06-09	46.9 <sup>H</sup>	21.4	1.01	13.6	6.5	-
Drug A	Visit 9	2025-07-04	32.6	22.5	1.21 <sup>H</sup>	13.9	5.2	+++
Drug A	Visit 10	2025-07-31	35.7	18.4	0.67	14.4	5.7	-

H, L - Value Outside Normal Ranges  
NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ019, Sex: M, Age (years): 64

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-06-23	35.2	30.5	1.12	12.0	6.6	-
Drug A	Visit 1	2024-07-09	55.8 <sup>H</sup>	48.0 <sup>H</sup>	0.68	16.9	5.5	-
Drug A	Visit 2	2024-07-19	27.0	14.8	0.80	12.6	5.7	+
Drug A	Visit 3	2024-08-02	25.1	31.6	1.37 <sup>H</sup>	14.1	6.3	-
Drug A	Visit 4	2024-08-21	22.8	36.2	1.31 <sup>H</sup>	12.2	6.5	-
Drug A	Visit 5	2024-09-15	21.3	32.3	0.94	18.3 <sup>H</sup>	5.7	+
Drug A	Visit 6	2024-10-10	17.8	18.9	1.46 <sup>H</sup>	11.5 <sup>L</sup>	5.1	-
Drug A	Visit 7	2024-11-09	23.9	40.3 <sup>H</sup>	0.74	15.7	6.8	-
Drug A	Visit 8	2024-12-07	16.8	39.6	0.64	10.8 <sup>L</sup>	6.1	-
Drug A	Visit 9	2025-01-04	20.5	10.3	0.45	15.0	6.0	-
Drug A	Visit 10	2025-02-02	25.3	20.3	1.20	12.4	6.1	++

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ020, Sex: F, Age (years): 57

Treatment	Visit	Date						
			ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-01-30	18.6	10.7	1.51 <sup>H</sup>	14.2	6.4	+
Drug A	Visit 1	2024-02-14	22.4	26.9	0.82	11.7 <sup>L</sup>	7.1	+++
Drug A	Visit 2	2024-02-26	32.7	31.7	0.87	12.9	5.4	-
Drug A	Visit 3	2024-03-09	23.0	47.1 <sup>H</sup>	0.74	16.7	6.2	-
Drug A	Visit 4	2024-03-28	27.2	34.9	0.97	14.6	6.8	+
Drug A	Visit 5	2024-04-24	19.5	16.9	0.75	14.8	5.9	-
Drug A	Visit 6	2024-05-18	29.9	24.0	0.69	14.7	5.5	+++
Drug A	Visit 7	2024-06-21	35.5	27.5	0.50	13.1	5.8	++
Drug A	Visit 8	2024-07-18	19.9	44.5 <sup>H</sup>	0.74	11.6 <sup>L</sup>	6.2	-
Drug A	Visit 9	2024-08-14	37.5	24.5	0.55	13.9	5.7	-
Drug A	Visit 10	2024-09-11	32.8	19.8	0.68	14.0	6.2	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ021, Sex: F, Age (years): 65

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-01-10	12.9	33.5	0.33	12.8	6.3	+
Drug A	Visit 1	2024-01-22	12.6	20.6	1.05	16.0	5.6	-
Drug A	Visit 2	2024-02-07	17.3	29.9	0.57	10.7 <sup>L</sup>	6.9	-
Drug A	Visit 3	2024-02-23	41.1 <sup>H</sup>	34.8	0.97	14.5	6.1	+++
Drug A	Visit 4	2024-03-08	38.7	29.1	1.00	14.4	6.1	++
Drug A	Visit 5	2024-04-06	29.0	24.9	0.45	13.6	5.6	-
Drug A	Visit 6	2024-04-28	15.3	30.1	0.78	13.0	5.7	+
Drug A	Visit 7	2024-05-27	15.2	28.0	1.00	15.3	5.4	++
Drug A	Visit 8	2024-06-29	26.9	24.1	1.50 <sup>H</sup>	12.9	6.1	-
Drug A	Visit 9	2024-07-21	30.9	23.4	0.44	15.4	6.3	+
Drug A	Visit 10	2024-08-19	16.0	27.6	0.74	12.4	6.8	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ022, Sex: F, Age (years): 20

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-01-22	14.6	21.0	1.20	14.1	6.4	-
Drug A	Visit 1	2024-02-03	31.2	19.4	0.46	15.6	6.1	+++
Drug A	Visit 2	2024-02-17	6.9 <sup>L</sup>	18.3	0.43	15.9	6.1	++
Drug A	Visit 3	2024-03-06	48.6 <sup>H</sup>	17.4	1.18	NC	5.6	++
Drug A	Visit 4	2024-03-21	22.0	27.0	0.80	11.4 <sup>L</sup>	6.0	-
Drug A	Visit 5	2024-04-12	16.4	28.9	0.69	12.5	NC	-
Drug A	Visit 6	2024-05-13	13.0	9.6 <sup>L</sup>	0.70	16.0	5.9	-
Drug A	Visit 7	2024-06-12	22.6	18.5	0.94	11.1 <sup>L</sup>	6.2	-
Drug A	Visit 8	2024-07-10	21.5	23.0	0.54	14.5	6.0	-
Drug A	Visit 9	2024-08-08	25.2	20.7	0.96	11.3 <sup>L</sup>	6.7	+
Drug A	Visit 10	2024-09-03	22.7	13.9	1.08	12.8	6.3	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ023, Sex: F, Age (years): 58

Treatment	Visit	Date						
			ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-02-18	23.4	17.6	1.23 <sup>H</sup>	14.3	5.1	-
Drug A	Visit 1	2024-03-02	29.3	23.9	0.50	15.6	6.4	-
Drug A	Visit 2	2024-03-17	38.4	38.3	0.71	13.2	7.0	+
Drug A	Visit 3	2024-04-02	14.9	24.3	0.92	14.6	5.9	+
Drug A	Visit 4	2024-04-12	23.9	24.4	0.85	13.7	5.0	++
Drug A	Visit 5	2024-05-11	34.0	14.0	0.92	14.6	6.9	-
Drug A	Visit 6	2024-06-08	23.7	22.1	0.75	15.5	6.2	-
Drug A	Visit 7	2024-07-09	32.3	67.5 <sup>H</sup>	0.56	15.5	5.3	-
Drug A	Visit 8	2024-08-07	15.7	24.9	1.49 <sup>H</sup>	14.3	6.5	-
Drug A	Visit 9	2024-09-02	24.1	15.3	0.68	13.3	6.3	-
Drug A	Visit 10	2024-10-02	29.2	18.6	1.49 <sup>H</sup>	13.8	5.3	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ024, Sex: M, Age (years): 49

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-12-10	56.1 <sup>H</sup>	27.5	0.84	13.9	5.9	+
Placebo	Visit 1	2024-12-21	24.8	16.6	0.58	16.1	5.2	+
Placebo	Visit 2	2025-01-05	33.0	21.3	0.27 <sup>L</sup>	14.9	5.7	-
Placebo	Visit 3	2025-01-23	39.4	40.5 <sup>H</sup>	1.26 <sup>H</sup>	15.2	5.6	+
Placebo	Visit 4	2025-02-06	31.5	29.5	0.67	13.2	6.4	-
Placebo	Visit 5	2025-03-05	14.8	25.2	0.62	15.4	5.7	+++
Placebo	Visit 6	2025-04-04	15.2	23.4	0.94	13.6	6.6	-
Placebo	Visit 7	2025-05-02	21.3	22.5	NC	13.5	6.3	++
Placebo	Visit 8	2025-05-24	30.1	30.2	0.89	15.4	6.2	++
Placebo	Visit 9	2025-06-21	21.2	35.2	0.42	13.9	6.3	-
Placebo	Visit 10	2025-07-21	24.0	18.4	0.60	13.9	5.4	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ025, Sex: F, Age (years): 59

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-03-20	26.2	38.4	0.67	9.4 <sup>L</sup>	5.8	-
Drug A	Visit 1	2024-04-01	15.5	39.8	0.89	14.0	6.5	-
Drug A	Visit 2	2024-04-15	18.2	20.5	1.44 <sup>H</sup>	13.6	5.8	-
Drug A	Visit 3	2024-05-04	18.8	36.8	0.61	14.6	6.4	+++
Drug A	Visit 4	2024-05-16	14.2	15.2	1.19	12.2	5.9	+
Drug A	Visit 5	2024-06-12	NC	18.1	0.65	13.4	6.5	++
Drug A	Visit 6	2024-07-07	32.5	20.9	0.68	14.5	6.8	+++
Drug A	Visit 7	2024-08-10	35.6	18.8	1.26 <sup>H</sup>	13.7	5.8	-
Drug A	Visit 8	2024-09-01	19.7	31.7	1.16	14.7	6.4	-
Drug A	Visit 9	2024-10-05	27.3	19.2	0.60	14.6	5.7	+++
Drug A	Visit 10	2024-10-27	52.6 <sup>H</sup>	19.8	0.74	15.2	5.2	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ026, Sex: M, Age (years): 60

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-03-13	17.4	43.0 <sup>H</sup>	0.54	10.3 <sup>L</sup>	5.2	-
Drug A	Visit 1	2024-03-27	17.1	20.5	0.82	14.3	6.2	-
Drug A	Visit 2	2024-04-07	NC	NC	NC	NC	NC	NC
Drug A	Visit 3	2024-04-27	26.5	12.2	1.40 <sup>H</sup>	13.3	6.2	-
Drug A	Visit 4	2024-05-08	31.9	17.7	0.71	14.4	5.3	-
Drug A	Visit 5	2024-06-07	NC	NC	NC	NC	NC	NC
Drug A	Visit 6	2024-07-05	23.4	23.5	0.53	15.4	6.0	-
Drug A	Visit 7	2024-08-03	NC	NC	NC	NC	NC	NC
Drug A	Visit 8	2024-08-31	31.4	10.3	0.67	14.7	6.0	-
Drug A	Visit 9	2024-09-22	15.2	24.3	0.56	13.7	6.4	-
Drug A	Visit 10	2024-10-26	10.3	18.1	0.78	13.4	6.5	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ027, Sex: F, Age (years): 19

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-05-27	27.7	14.2	0.59	15.1	6.1	-
Placebo	Visit 1	2024-06-09	24.9	18.6	1.24 <sup>H</sup>	12.5	5.9	-
Placebo	Visit 2	2024-06-24	21.8	22.8	0.57	14.4	6.0	+
Placebo	Visit 3	2024-07-09	31.0	33.6	0.42	14.2	5.8	++
Placebo	Visit 4	2024-07-25	19.7	15.4	1.61 <sup>H</sup>	10.4 <sup>L</sup>	6.1	-
Placebo	Visit 5	2024-08-22	20.4	30.5	0.98	14.4	5.8	-
Placebo	Visit 6	2024-09-19	17.7	10.4	0.74	13.6	6.3	++
Placebo	Visit 7	2024-10-15	18.8	27.1	0.52	14.5	6.5	-
Placebo	Visit 8	2024-11-14	19.9	23.4	0.54	12.6	6.4	+++
Placebo	Visit 9	2024-12-09	33.8	53.5 <sup>H</sup>	0.89	13.7	5.9	+++
Placebo	Visit 10	2025-01-09	35.1	37.2	1.09	14.8	5.3	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ028, Sex: M, Age (years): 71

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-01-12	34.2	19.3	0.64	12.7	6.3	-
Drug A	Visit 1	2024-01-25	39.9	16.2	0.52	14.8	6.2	-
Drug A	Visit 2	2024-02-11	26.2	21.8	0.80	17.3 <sup>H</sup>	6.0	-
Drug A	Visit 3	2024-02-24	26.5	20.1	0.57	18.4 <sup>H</sup>	6.6	-
Drug A	Visit 4	2024-03-11	15.0	21.5	0.98	15.6	6.2	-
Drug A	Visit 5	2024-04-06	26.6	11.5	0.63	13.4	6.2	+
Drug A	Visit 6	2024-05-04	51.9 <sup>H</sup>	26.4	1.33 <sup>H</sup>	18.5 <sup>H</sup>	5.9	-
Drug A	Visit 7	2024-06-03	17.7	30.7	1.06	14.2	6.8	-
Drug A	Visit 8	2024-06-27	16.3	29.4	0.92	12.3	6.2	-
Drug A	Visit 9	2024-07-29	20.9	18.2	0.97	15.7	5.7	-
Drug A	Visit 10	2024-08-20	25.2	31.3	1.37 <sup>H</sup>	11.4 <sup>L</sup>	5.7	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ029, Sex: M, Age (years): 66

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-10-19	14.0	24.4	0.38	14.1	6.3	-
Placebo	Visit 1	2024-11-03	21.2	33.4	0.69	15.9	5.8	-
Placebo	Visit 2	2024-11-14	34.6	23.6	0.75	14.2	6.6	-
Placebo	Visit 3	2024-11-30	12.9	17.9	0.65	12.4	6.7	+
Placebo	Visit 4	2024-12-13	11.3	24.4	1.13	16.2	5.3	-
Placebo	Visit 5	2025-01-13	21.1	33.2	2.42 <sup>H</sup>	15.2	5.9	-
Placebo	Visit 6	2025-02-09	23.8	23.0	1.53 <sup>H</sup>	14.8	6.1	+++
Placebo	Visit 7	2025-03-09	72.2 <sup>H</sup>	16.0	0.84	15.2	5.7	++
Placebo	Visit 8	2025-04-07	24.0	21.5	0.93	13.1	6.1	-
Placebo	Visit 9	2025-05-01	17.9	17.6	0.51	14.9	6.0	-
Placebo	Visit 10	2025-05-29	38.3	25.3	1.45 <sup>H</sup>	14.4	5.4	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ030, Sex: F, Age (years): 73

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-12-02	15.6	23.6	0.64	15.2	5.7	-
Drug A	Visit 1	2024-12-13	16.9	13.8	0.38	14.3	4.9	-
Drug A	Visit 2	2024-12-29	46.7 <sup>H</sup>	27.5	0.45	16.2	5.7	-
Drug A	Visit 3	2025-01-12	19.9	14.8	0.87	14.8	6.5	+++
Drug A	Visit 4	2025-01-26	18.1	29.3	1.34 <sup>H</sup>	15.9	5.7	-
Drug A	Visit 5	2025-02-22	14.5	25.1	1.14	11.9 <sup>L</sup>	6.4	++
Drug A	Visit 6	2025-03-21	47.4 <sup>H</sup>	18.9	0.69	13.9	6.4	+
Drug A	Visit 7	2025-04-18	22.9	21.8	0.92	12.7	7.0	-
Drug A	Visit 8	2025-05-18	33.5	25.2	0.69	11.3 <sup>L</sup>	6.2	-
Drug A	Visit 9	2025-06-19	21.6	24.5	1.15	13.5	5.8	-
Drug A	Visit 10	2025-07-17	23.9	13.1	0.74	15.3	6.6	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ031, Sex: F, Age (years): 68

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-07-13	10.4	19.2	1.13	13.7	6.2	+
Placebo	Visit 1	2024-07-25	7.4 <sup>L</sup>	19.1	1.41 <sup>H</sup>	15.8	6.3	-
Placebo	Visit 2	2024-08-11	17.1	33.1	0.59	14.2	5.3	NC
Placebo	Visit 3	2024-08-25	50.0 <sup>H</sup>	NC	0.68	14.6	6.5	-
Placebo	Visit 4	2024-09-09	14.8	28.4	0.79	15.4	6.1	+
Placebo	Visit 5	2024-10-08	7.5 <sup>L</sup>	18.4	0.75	17.0	6.3	-
Placebo	Visit 6	2024-11-01	23.8	7.3 <sup>L</sup>	1.07	14.1	6.2	-
Placebo	Visit 7	2024-12-01	25.1	43.2 <sup>H</sup>	0.59	12.0	5.6	-
Placebo	Visit 8	2024-12-27	27.9	32.9	0.59	13.9	6.4	-
Placebo	Visit 9	2025-01-25	NC	NC	NC	NC	NC	NC
Placebo	Visit 10	2025-02-25	7.3 <sup>L</sup>	74.4 <sup>H</sup>	1.11	13.9	6.8	+

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ032, Sex: M, Age (years): 23

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-10-29	14.1	9.0 <sup>L</sup>	0.61	12.9	6.2	+
Drug A	Visit 1	2024-11-14	31.2	26.1	1.17	15.9	5.8	+++
Drug A	Visit 2	2024-11-28	28.5	26.2	1.12	14.5	6.2	++
Drug A	Visit 3	2024-12-12	27.0	30.3	0.98	15.5	5.8	-
Drug A	Visit 4	2024-12-27	14.7	41.0 <sup>H</sup>	0.43	14.4	5.4	-
Drug A	Visit 5	2025-01-19	24.7	20.0	0.80	14.1	6.1	-
Drug A	Visit 6	2025-02-15	21.6	19.5	0.76	13.9	5.8	-
Drug A	Visit 7	2025-03-18	24.4	19.0	0.74	15.6	5.4	-
Drug A	Visit 8	2025-04-17	24.3	21.7	1.26 <sup>H</sup>	13.7	5.4	-
Drug A	Visit 9	2025-05-10	11.3	18.9	0.87	15.0	6.2	-
Drug A	Visit 10	2025-06-12	30.2	33.4	0.59	13.8	6.4	-

H, L - Value Outside Normal Ranges  
NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ033, Sex: F, Age (years): 66

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-03-26	16.8	20.6	1.38 <sup>H</sup>	13.7	6.9	-
Drug A	Visit 1	2024-04-07	30.3	22.0	0.64	12.1	6.8	-
Drug A	Visit 2	2024-04-20	45.6 <sup>H</sup>	34.2	0.53	13.6	5.8	-
Drug A	Visit 3	2024-05-08	17.2	40.8 <sup>H</sup>	0.93	10.5 <sup>L</sup>	6.5	-
Drug A	Visit 4	2024-05-20	52.0 <sup>H</sup>	29.2	0.65	14.2	6.0	-
Drug A	Visit 5	2024-06-19	24.6	13.8	0.62	14.6	5.9	-
Drug A	Visit 6	2024-07-19	29.6	24.1	0.77	16.0	6.3	-
Drug A	Visit 7	2024-08-15	19.4	19.9	0.39	16.1	6.1	-
Drug A	Visit 8	2024-09-13	10.4	42.5 <sup>H</sup>	0.50	13.2	5.0	-
Drug A	Visit 9	2024-10-07	21.4	27.1	0.88	11.6 <sup>L</sup>	5.6	+
Drug A	Visit 10	2024-11-05	22.7	37.7	0.66	13.4	5.5	+

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ034, Sex: M, Age (years): 66

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-06-14	21.9	14.3	0.79	16.4	5.4	-
Placebo	Visit 1	2024-06-29	45.1 <sup>H</sup>	25.4	0.73	14.5	5.6	-
Placebo	Visit 2	2024-07-13	16.7	35.2	0.62	14.2	5.9	+
Placebo	Visit 3	2024-07-25	18.6	24.3	1.01	12.1	5.4	-
Placebo	Visit 4	2024-08-07	14.5	38.0	0.98	13.8	6.0	-
Placebo	Visit 5	2024-09-08	52.3 <sup>H</sup>	26.8	0.88	14.2	5.3	-
Placebo	Visit 6	2024-10-04	39.7	22.4	0.63	15.9	6.4	-
Placebo	Visit 7	2024-10-31	16.5	29.4	0.62	14.7	6.2	++
Placebo	Visit 8	2024-11-28	48.0 <sup>H</sup>	27.6	1.32 <sup>H</sup>	14.3	6.3	-
Placebo	Visit 9	2024-12-24	26.2	25.2	0.93	15.3	5.8	-
Placebo	Visit 10	2025-01-24	16.0	10.8	0.53	14.2	5.9	+++

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ035, Sex: F, Age (years): 74

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-12-03	47.2 <sup>H</sup>	23.3	0.83	16.3	6.3	-
Drug A	Visit 1	2024-12-19	48.4 <sup>H</sup>	13.6	0.76	13.3	6.3	-
Drug A	Visit 2	2024-12-30	22.6	7.1 <sup>L</sup>	0.62	15.1	6.3	-
Drug A	Visit 3	2025-01-15	40.2 <sup>H</sup>	22.3	1.34 <sup>H</sup>	14.2	6.5	-
Drug A	Visit 4	2025-01-26	39.2	35.7	1.22 <sup>H</sup>	12.9	6.8	-
Drug A	Visit 5	2025-02-24	10.2	11.9	0.80	12.0	5.6	-
Drug A	Visit 6	2025-03-27	84.5 <sup>H</sup>	18.0	0.46	14.2	5.7	+
Drug A	Visit 7	2025-04-25	15.0	18.0	0.72	14.0	6.6	-
Drug A	Visit 8	2025-05-20	24.6	12.1	0.65	11.9 <sup>L</sup>	5.8	++
Drug A	Visit 9	2025-06-20	19.6	15.0	1.12	16.1	6.7	-
Drug A	Visit 10	2025-07-12	18.6	21.0	0.54	15.2	6.1	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ036, Sex: F, Age (years): 25

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-12-15	37.3	16.5	0.94	16.9	5.8	-
Drug A	Visit 1	2025-01-01	23.4	19.4	1.50 <sup>H</sup>	13.8	6.3	-
Drug A	Visit 2	2025-01-15	11.3	19.9	1.23 <sup>H</sup>	14.7	5.2	+
Drug A	Visit 3	2025-01-28	29.2	21.2	0.49	12.6	6.7	-
Drug A	Visit 4	2025-02-07	32.0	18.2	0.86	14.3	6.7	-
Drug A	Visit 5	2025-03-12	18.6	21.7	0.44	14.9	5.4	-
Drug A	Visit 6	2025-04-07	15.7	26.2	1.50 <sup>H</sup>	13.8	6.3	-
Drug A	Visit 7	2025-05-06	37.7	36.2	1.26 <sup>H</sup>	16.1	6.3	-
Drug A	Visit 8	2025-06-02	16.9	21.3	0.41	11.2 <sup>L</sup>	5.1	-
Drug A	Visit 9	2025-06-30	20.8	13.2	0.66	13.1	5.5	-
Drug A	Visit 10	2025-07-30	25.6	31.3	0.98	15.4	6.1	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ037, Sex: F, Age (years): 43

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-05-26	28.3	21.9	0.58	16.3	6.1	-
Drug A	Visit 1	2024-06-10	44.8 <sup>H</sup>	11.6	0.81	13.8	6.0	-
Drug A	Visit 2	2024-06-26	28.5	28.9	0.75	11.5 <sup>L</sup>	5.2	+
Drug A	Visit 3	2024-07-07	16.7	33.7	1.12	13.4	6.2	-
Drug A	Visit 4	2024-07-19	16.8	31.1	1.07	15.1	5.6	+
Drug A	Visit 5	2024-08-16	37.1	27.6	0.42	13.8	5.9	-
Drug A	Visit 6	2024-09-12	23.0	16.0	1.06	14.9	6.5	-
Drug A	Visit 7	2024-10-11	16.0	27.2	0.55	14.2	5.6	-
Drug A	Visit 8	2024-11-10	22.8	28.9	1.72 <sup>H</sup>	14.9	6.3	++
Drug A	Visit 9	2024-12-06	29.7	29.2	NC	14.1	5.4	++
Drug A	Visit 10	2025-01-07	75.4 <sup>H</sup>	26.9	1.03	14.4	5.4	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ038, Sex: F, Age (years): 34

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-05-25	19.4	17.1	0.61	11.6 <sup>L</sup>	5.4	+++
Drug A	Visit 1	2024-06-06	25.0	16.4	0.92	12.3	5.4	-
Drug A	Visit 2	2024-06-24	18.7	14.7	0.97	15.8	6.6	-
Drug A	Visit 3	2024-07-05	25.1	NC	0.73	15.0	6.0	-
Drug A	Visit 4	2024-07-19	19.0	27.6	1.11	12.0	6.9	++
Drug A	Visit 5	2024-08-14	29.2	23.8	0.99	12.5	6.0	-
Drug A	Visit 6	2024-09-11	40.6 <sup>H</sup>	30.4	0.43	13.1	6.4	-
Drug A	Visit 7	2024-10-11	33.8	23.8	0.89	14.6	6.5	-
Drug A	Visit 8	2024-11-06	28.1	24.5	0.91	12.5	5.7	-
Drug A	Visit 9	2024-12-05	27.6	16.4	2.13 <sup>H</sup>	11.7 <sup>L</sup>	6.2	-
Drug A	Visit 10	2025-01-05	27.2	29.3	0.86	13.2	5.9	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ039, Sex: M, Age (years): 80

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-04-16	24.6	19.5	0.69	11.2 <sup>L</sup>	5.6	-
Drug A	Visit 1	2024-04-30	18.4	36.4	1.02	15.4	6.1	-
Drug A	Visit 2	2024-05-13	16.5	15.7	1.05	12.9	6.0	-
Drug A	Visit 3	2024-05-26	32.7	25.4	0.60	14.0	5.7	-
Drug A	Visit 4	2024-06-11	20.8	24.1	1.15	13.6	6.3	+
Drug A	Visit 5	2024-07-12	26.4	32.4	0.36	14.6	6.3	-
Drug A	Visit 6	2024-08-09	29.2	32.0	0.71	14.1	5.9	+
Drug A	Visit 7	2024-09-03	47.1 <sup>H</sup>	12.2	0.83	14.2	5.6	++
Drug A	Visit 8	2024-10-01	12.6	13.3	0.55	12.7	6.4	-
Drug A	Visit 9	2024-10-31	18.5	15.7	0.55	13.8	NC	+
Drug A	Visit 10	2024-11-25	16.1	29.1	0.61	16.6	6.6	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ040, Sex: M, Age (years): 25

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-08-27	135.4 <sup>H</sup>	80.7 <sup>H</sup>	1.49 <sup>H</sup>	14.1	5.2	-
Drug A	Visit 1	2024-09-11	NC	NC	NC	NC	NC	NC
Drug A	Visit 2	2024-09-23	112.5 <sup>H</sup>	158.8 <sup>H</sup>	0.70	15.4	6.5	+
Drug A	Visit 3	2024-10-08	66.3 <sup>H</sup>	83.1 <sup>H</sup>	0.43	12.8	5.3	-
Drug A	Visit 4	2024-10-25	76.7 <sup>H</sup>	91.2 <sup>H</sup>	1.04	13.5	5.1	-
Drug A	Visit 5	2024-11-19	167.7 <sup>H</sup>	106.4 <sup>H</sup>	0.70	11.1 <sup>L</sup>	5.7	-
Drug A	Visit 6	2024-12-16	104.6 <sup>H</sup>	73.8 <sup>H</sup>	1.38 <sup>H</sup>	13.7	6.4	+
Drug A	Visit 7	2025-01-17	84.4 <sup>H</sup>	92.1 <sup>H</sup>	0.50	15.1	6.6	+
Drug A	Visit 8	2025-02-08	111.0 <sup>H</sup>	116.1 <sup>H</sup>	0.70	13.3	6.2	+
Drug A	Visit 9	2025-03-14	143.5 <sup>H</sup>	92.8 <sup>H</sup>	0.89	14.4	5.0	++
Drug A	Visit 10	2025-04-07	129.7 <sup>H</sup>	98.6 <sup>H</sup>	0.89	15.5	5.5	+

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ041, Sex: F, Age (years): 39

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-01-31	19.9	39.1	0.93	13.7	6.0	-
Placebo	Visit 1	2024-02-11	NC	NC	NC	NC	NC	NC
Placebo	Visit 2	2024-02-26	30.5	19.3	0.54	13.8	5.9	-
Placebo	Visit 3	2024-03-16	16.8	35.2	0.59	13.6	5.9	-
Placebo	Visit 4	2024-03-30	21.4	29.1	0.75	14.5	5.5	-
Placebo	Visit 5	2024-04-25	27.4	57.9 <sup>H</sup>	1.43 <sup>H</sup>	16.3	5.6	-
Placebo	Visit 6	2024-05-24	13.9	31.7	0.83	11.9 <sup>L</sup>	6.7	-
Placebo	Visit 7	2024-06-16	23.5	51.9 <sup>H</sup>	0.88	12.2	6.2	+++
Placebo	Visit 8	2024-07-15	NC	NC	NC	NC	NC	NC
Placebo	Visit 9	2024-08-12	27.1	23.7	0.48	12.9	6.1	-
Placebo	Visit 10	2024-09-13	20.5	20.8	0.52	12.6	6.4	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ042, Sex: M, Age (years): 52

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-01-06	40.3 <sup>H</sup>	30.6	0.77	11.8 <sup>L</sup>	6.1	+
Drug A	Visit 1	2024-01-23	27.7	15.8	1.04	11.3 <sup>L</sup>	5.6	+
Drug A	Visit 2	2024-02-01	9.4 <sup>L</sup>	11.5	0.85	14.1	6.3	-
Drug A	Visit 3	2024-02-20	21.1	27.2	0.72	16.6	5.9	-
Drug A	Visit 4	2024-03-03	36.3	23.6	1.15	12.7	5.6	-
Drug A	Visit 5	2024-03-29	22.5	16.3	0.45	12.6	6.0	-
Drug A	Visit 6	2024-04-27	22.1	20.0	0.86	13.2	5.5	+
Drug A	Visit 7	2024-05-26	19.6	20.5	1.39 <sup>H</sup>	13.3	6.2	-
Drug A	Visit 8	2024-06-23	43.0 <sup>H</sup>	30.3	0.89	15.8	5.1	-
Drug A	Visit 9	2024-07-20	34.0	18.5	0.86	13.8	7.1	-
Drug A	Visit 10	2024-08-15	17.2	15.9	0.43	14.3	5.8	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ043, Sex: M, Age (years): 58

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-09-19	41.0 <sup>H</sup>	21.0	0.54	11.0 <sup>L</sup>	5.9	-
Placebo	Visit 1	2024-10-02	24.7	18.4	0.58	13.4	6.6	-
Placebo	Visit 2	2024-10-18	20.6	33.0	0.71	14.8	6.2	-
Placebo	Visit 3	2024-10-31	39.1	14.4	0.41	16.4	6.6	-
Placebo	Visit 4	2024-11-16	21.9	20.0	0.67	15.4	5.9	-
Placebo	Visit 5	2024-12-10	26.3	42.6 <sup>H</sup>	0.89	13.8	5.9	-
Placebo	Visit 6	2025-01-12	23.0	22.8	1.08	12.3	4.9	-
Placebo	Visit 7	2025-02-03	15.4	29.9	1.11	13.7	5.6	++
Placebo	Visit 8	2025-03-03	39.0	17.3	0.84	15.5	5.4	-
Placebo	Visit 9	2025-04-04	13.8	31.3	1.13	12.6	6.2	+
Placebo	Visit 10	2025-04-30	14.3	35.5	0.67	11.5 <sup>L</sup>	6.1	-

H, L - Value Outside Normal Ranges  
NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ044, Sex: F, Age (years): 20

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-11-23	14.8	14.1	0.78	15.9	5.6	-
Drug A	Visit 1	2024-12-09	27.4	15.3	0.79	13.7	5.2	-
Drug A	Visit 2	2024-12-18	15.8	16.4	1.33 <sup>H</sup>	12.7	5.6	-
Drug A	Visit 3	2025-01-05	20.3	16.6	0.71	13.3	5.5	-
Drug A	Visit 4	2025-01-16	9.4 <sup>L</sup>	33.3	0.90	13.2	5.7	-
Drug A	Visit 5	2025-02-12	19.3	12.1	1.39 <sup>H</sup>	16.8	6.0	+++
Drug A	Visit 6	2025-03-13	24.1	37.8	1.13	15.4	6.5	-
Drug A	Visit 7	2025-04-15	24.8	15.9	1.19	11.6 <sup>L</sup>	5.7	++
Drug A	Visit 8	2025-05-13	19.6	26.8	0.52	14.1	6.5	+++
Drug A	Visit 9	2025-06-08	17.7	38.8	0.35	13.9	6.4	-
Drug A	Visit 10	2025-07-07	18.5	10.6	0.69	11.6 <sup>L</sup>	6.3	++

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ045, Sex: F, Age (years): 74

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-01-04	17.9	35.0	0.92	16.5	6.3	+
Placebo	Visit 1	2024-01-21	NC	23.5	0.41	13.0	5.6	-
Placebo	Visit 2	2024-02-03	16.2	26.8	0.67	13.9	6.6	-
Placebo	Visit 3	2024-02-16	48.2 <sup>H</sup>	17.2	0.96	16.3	5.9	+
Placebo	Visit 4	2024-03-03	23.9	34.2	0.67	15.9	5.4	-
Placebo	Visit 5	2024-03-29	42.7 <sup>H</sup>	14.9	0.96	11.8 <sup>L</sup>	7.3	-
Placebo	Visit 6	2024-04-22	51.6 <sup>H</sup>	29.4	1.00	12.2	5.6	-
Placebo	Visit 7	2024-05-21	22.5	12.2	0.74	15.2	6.5	-
Placebo	Visit 8	2024-06-23	20.1	29.0	0.88	13.7	5.9	-
Placebo	Visit 9	2024-07-16	22.9	34.1	0.65	13.6	6.0	-
Placebo	Visit 10	2024-08-12	59.7 <sup>H</sup>	20.6	0.57	12.8	6.1	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ046, Sex: F, Age (years): 27

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-02-12	43.0 <sup>H</sup>	12.9	0.71	14.4	6.5	-
Placebo	Visit 1	2024-02-28	34.5	31.2	0.86	13.7	5.3	-
Placebo	Visit 2	2024-03-12	31.0	27.1	0.72	13.0	6.4	-
Placebo	Visit 3	2024-03-27	40.0	12.9	0.51	14.9	5.8	-
Placebo	Visit 4	2024-04-06	10.9	32.6	0.95	13.2	5.4	-
Placebo	Visit 5	2024-05-03	40.3 <sup>H</sup>	16.0	1.25 <sup>H</sup>	16.5	6.5	-
Placebo	Visit 6	2024-05-31	20.3	26.4	0.93	13.8	5.6	++
Placebo	Visit 7	2024-06-29	26.8	30.5	1.12	14.3	6.2	++
Placebo	Visit 8	2024-07-31	16.0	34.0	0.63	13.1	7.0	+
Placebo	Visit 9	2024-08-25	38.5	15.3	1.76 <sup>H</sup>	14.7	5.7	-
Placebo	Visit 10	2024-09-25	37.6	31.8	0.40	14.0	6.8	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ047, Sex: F, Age (years): 72

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Drug A	Baseline	2024-07-07	11.7	14.3	0.59	14.3	5.9	-
Drug A	Visit 1	2024-07-21	22.1	25.9	0.56	15.6	6.2	++
Drug A	Visit 2	2024-08-04	29.3	42.3 <sup>H</sup>	1.02	15.0	6.1	-
Drug A	Visit 3	2024-08-15	11.8	23.4	0.80	15.3	5.8	-
Drug A	Visit 4	2024-09-04	38.1	8.1 <sup>L</sup>	0.95	15.8	6.7	-
Drug A	Visit 5	2024-10-02	45.6 <sup>H</sup>	12.5	0.57	15.2	5.7	-
Drug A	Visit 6	2024-10-28	12.3	38.4	1.34 <sup>H</sup>	12.5	6.4	-
Drug A	Visit 7	2024-11-22	19.1	41.1 <sup>H</sup>	0.35	12.9	5.7	-
Drug A	Visit 8	2024-12-25	21.2	29.1	1.00	15.5	5.9	-
Drug A	Visit 9	2025-01-21	19.7	18.0	0.61	15.1	5.4	-
Drug A	Visit 10	2025-02-14	34.8	21.2	0.69	13.2	5.3	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ048, Sex: F, Age (years): 39

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-06-19	NC	NC	NC	NC	NC	NC
Placebo	Visit 1	2024-06-30	52.2 <sup>H</sup>	18.0	NC	14.9	6.3	++
Placebo	Visit 2	2024-07-19	23.8	24.9	0.63	14.5	6.0	-
Placebo	Visit 3	2024-07-30	30.3	37.5	0.50	12.6	6.3	-
Placebo	Visit 4	2024-08-15	17.9	16.1	0.77	13.5	6.1	-
Placebo	Visit 5	2024-09-11	21.2	41.7 <sup>H</sup>	1.00	15.1	6.4	-
Placebo	Visit 6	2024-10-11	31.3	17.9	1.46 <sup>H</sup>	14.1	5.3	-
Placebo	Visit 7	2024-11-03	33.2	12.4	0.52	14.5	6.1	NC
Placebo	Visit 8	2024-12-07	38.2	25.4	0.99	14.4	5.0	+
Placebo	Visit 9	2025-01-01	15.7	26.1	0.49	16.5	5.7	-
Placebo	Visit 10	2025-01-28	26.7	41.1 <sup>H</sup>	0.96	15.8	6.1	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ049, Sex: M, Age (years): 42

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-02-08	27.8	15.6	0.74	13.3	5.4	-
Placebo	Visit 1	2024-02-20	30.4	28.7	0.45	12.8	6.9	-
Placebo	Visit 2	2024-03-06	31.8	30.0	0.79	11.9 <sup>L</sup>	7.2	+
Placebo	Visit 3	2024-03-18	13.2	8.6 <sup>L</sup>	0.79	11.7 <sup>L</sup>	6.0	++
Placebo	Visit 4	2024-04-06	15.1	33.5	0.81	15.0	6.1	-
Placebo	Visit 5	2024-04-30	NC	NC	NC	NC	NC	NC
Placebo	Visit 6	2024-06-01	23.8	23.2	0.87	13.3	6.1	++
Placebo	Visit 7	2024-06-29	34.5	32.3	0.75	14.3	6.7	+
Placebo	Visit 8	2024-07-26	56.0 <sup>H</sup>	12.3	0.79	14.3	6.4	-
Placebo	Visit 9	2024-08-23	35.4	13.3	0.94	15.3	5.3	-
Placebo	Visit 10	2024-09-17	28.4	32.2	1.05	17.1 <sup>H</sup>	6.4	++

H, L - Value Outside Normal Ranges  
 NC - Not Collected

**Listing 16.1**  
**Laboratory Data**

Subject: SUBJ050, Sex: F, Age (years): 20

Treatment	Visit	Date	ALT (U/L)	AST (U/L)	Bilirubin (g/dL)	Hemoglobin (g/dL)	pH	Leukocytes, urine (/HPF)
Placebo	Baseline	2024-10-24	105.3 <sup>H</sup>	16.0	0.90	11.9 <sup>L</sup>	6.4	-
Placebo	Visit 1	2024-11-06	14.6	26.9	0.49	13.7	5.6	-
Placebo	Visit 2	2024-11-24	19.1	36.3	0.95	13.5	5.2	-
Placebo	Visit 3	2024-12-05	12.9	31.2	1.09	16.0	6.0	++
Placebo	Visit 4	2024-12-19	19.2	17.1	0.93	14.4	6.0	-
Placebo	Visit 5	2025-01-19	21.4	39.8	1.28 <sup>H</sup>	13.6	5.1	-
Placebo	Visit 6	2025-02-10	22.8	38.7	0.74	17.5 <sup>H</sup>	7.2	-
Placebo	Visit 7	2025-03-13	40.6 <sup>H</sup>	26.3	0.83	12.9	5.8	-
Placebo	Visit 8	2025-04-12	38.0	18.8	0.61	11.8 <sup>L</sup>	5.6	-
Placebo	Visit 9	2025-05-09	30.8	19.7	0.62	13.4	6.0	-
Placebo	Visit 10	2025-06-02	32.6	16.3	1.40 <sup>H</sup>	15.4	6.0	-

H, L - Value Outside Normal Ranges  
 NC - Not Collected