HUMIC ACID

EFFICACY FOR TREATMENT OF CHRONIC HEPATITIS C

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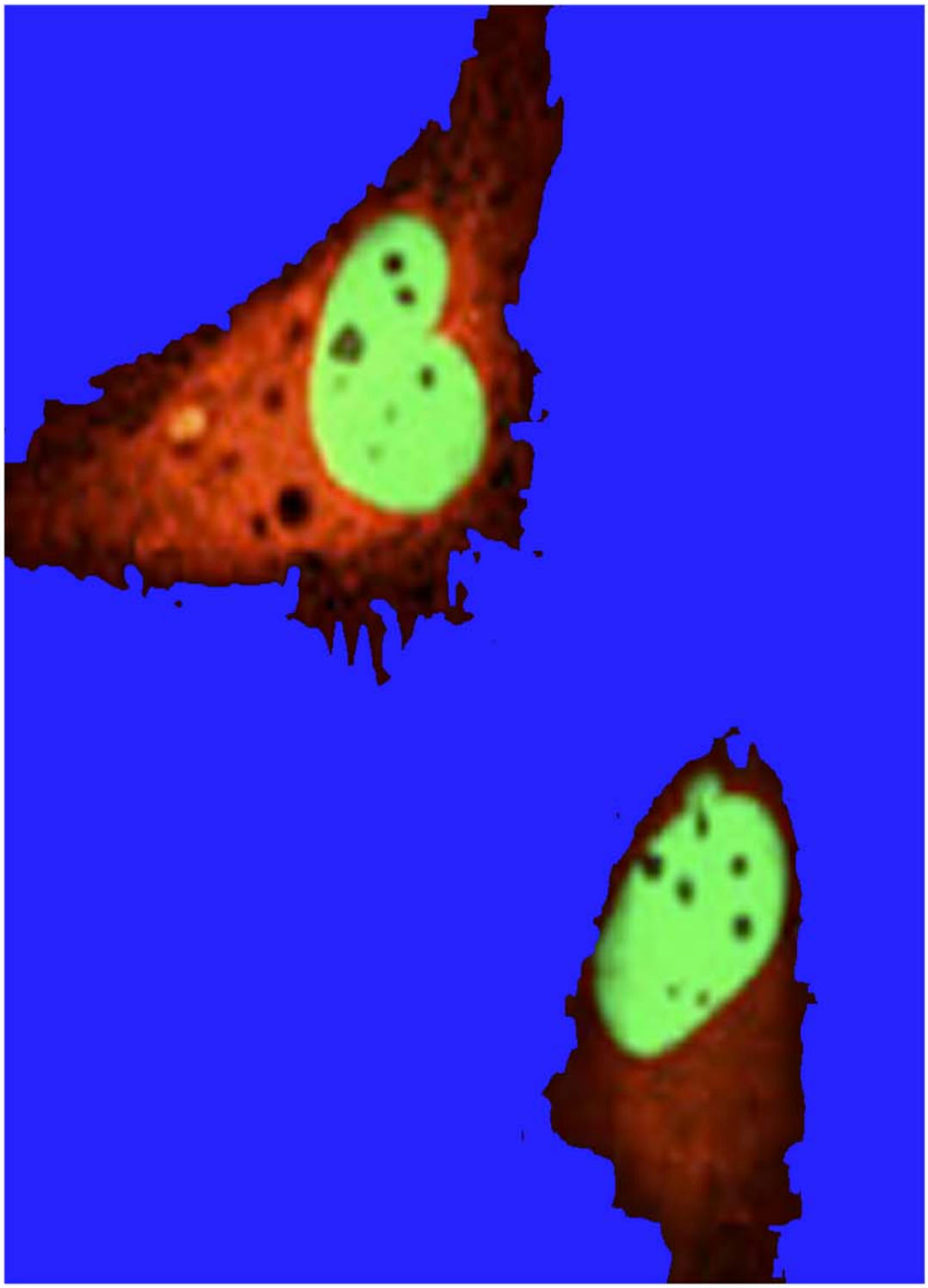
April 2006



FRONTISPIECE*: *In liver cell nuclei a protein called CREBH (green) turns on the activity of specific inflammatory-response genes as a result of cellular stress (e.g., infection).

Forward

This Report documents the progression of hepatitis C in a patient treated specifically for this disease. The origin of the infection is unclear, although notes indicate that the patient suffered from chronic hepatitis C. A liver biopsy confirmed the presence of hepatitis C and associated mild liver inflammatory activity (grade 2/4). Following biopsy, treatment consisting of weekly injections of pegylated interferon alpha-2a ("Pegasys") in conjunction with the administration of ribavirin and humic acid was initiated.

Interferon was begun following the initial diagnosis, and was continued thereafter once per week for 9 months.

Ribavirin treatment (200 mg/tablet) was begun simultaneously with interferon administration. The dose was 3 tablets in the morning and 3 tablets in the evening, which was carried out for 9 months.

Humic acid was administered in tablet form (250 mg/tablet), commensurate with the administration of interferon and ribavirin. Two tablets were taken in the morning and two in the evening, for 9 months. Humic acid treatment was thereafter reduced to one tablet in the morning and one in the evening.

The patient was a male Hispanic-Caucasian, age 43, in otherwise-good condition.

The preparation of natural-product and synthetic humate materials is described in U.S. patents 5,946,445; 6,569,416; 6,524,566; 6,524,567; 6,534,049; 6,576,229; and in other U.S. and international patents and patents pending.

Table of Contents

RAW BLOOD DATA

Coverage: 514 Days

Date/Time Collected: 10/07/2003 07:00 PM

Blood Chemistry/Immunology

Test Name	Results	Reference Range	Flag
Cholesterol	227 mg/dl	120 mg/dl - 210 mg/dl	*HIGH*
HDL Cholesterol	51 mg/dl	31 mg/dl - 85 mg/dl	
Cholesterol Ratio	4.5 %	0.0 % - 5.0 %	
LDL	148 mg/dl	70 mg/dl - 194 mg/dl	
LDL/HDL Ratio	2.90 mg/dl	0.96 mg/dl - 6.06 mg/dl	
Triglycerides	139 mg/dl	10 mg/dl - 190 mg/dl	
Glucose	43 mg/dl	70 mg/dl - 125 mg/dl	*LOW*
Fructosamine	1.3 mmol/l	1.2 mmol/l - 2.1 mmol/l	
SGOT(AST)	59 U/L	0 U/L - 41 U/L	*HIGH*
SGPT(ALT)	113 U/L	0 U/L - 45 U/L	*HIGH*
GGT(GGTP)	79 U/L	0 U/L - 65 U/L	*HIGH*
Alkaline Phosphatase	71 U/L	30 U/L - 115 U/L	
Total Bilirubin	0.8 mg/dl	0.1 mg/dl - 1.2 mg/dl	
Albumin	4.6 g/dl	3.7 g/dl - 4.7 g/dl	
BUN	14 mg/dl	5 mg/dl - 25 mg/dl	
Creatinine	1.0 mg/dl	0.5 mg/dl - 1.5 mg/dl	
Total Protein	8.0 g/dl	6.3 g/dl - 8.2 g/dl	
Globulin	3.4 g/dl	2.3 g/dl - 3.9 g/dl	
Serum HIV	NEG		
HEP B SURFAC ANTIGEN	NEG		
Hepatitis C	POS		Abnormal

Urinalysis

Test Name	Results	Reference Range	Flag
Glucose quantitative	0.00 gm%	0.00 gm% - 0.50 gm%	
Gcast Micro Exam	0 /40LPF	0 /40LPF - 0 /40LPF	
Hcast Micro Exam	0	0 - 40	
RBC Micro Exam	0 /HPF	0 /HPF - 4 /HPF	
WBC Micro Exam	30 /HPF	0 /HPF - 9 /HPF	*HIGH*
Cotinine (Nicotine)	NEG		
Cocaine	NEG		
Protein	0	0 - 30	
Adult. Creatinine	36.0 mg/dl	0.0 mg/dl - 300.0 mg/dl	
Adulterant PH	6.5	4.0 - 8.7	

NO LIPEMIA
NO HEMOLYSIS
A STUDY OF 70 HCV EIA REACTIVE SPECIMENS REPEATED USING HCV RIBA VERSION 3.0 CONFIRMATION YIELDED THE FOLLOWING RESULTS:

EIA REACTIVITY	RIBA NEGATIVE	RIBA INDETERMINATE	RIBA POSITIVE
WEAK POS.	19/25(76%)	6/25(24%)	0/25(0%)
MOD. POS.	5/10(50%)	3/10(30%)	2/10(20%)
STRONG POS.	0/35(0%)	1/35(3%)	34/35(97%)

HCV VERSION 3.0 WITH HCV RIBA VERSION 3.0 CONFIRMATION REPRESENTS THE MOST SENSITIVE AND SPECIFIC METHOD FOR DETERMINING HCV INFECTION. USE CAUTION WHEN COMPARING THESE RESULTS WITH METHODS OF LESSER SENSITIVITY. HEPATITIS C RIBA VERSION 3.0 CONFIRMATION

REQUESTING PHYSICIAN

11/03/03

ORDER MD:
CONSULT MD(s):
CONSULT MD(s):

Pull Chart ____	Review Complete ____
Initials ____	Initials ____
Date ____	Date ____

DRAW DATE / TIME

CHEMICAL PATHOLOGY

31OCT03 NONE

GLUCOSE METABOLISM			UNITS	REFERENCE
HGB A1C	5.4	f	%	[4.1-6.5]
MBG EST.	94		MG/DL	

HGB A1C | Hemoglobin A1C determined by an immunoturbidimetric metho
| Please note: Hemoglobin variants may result in HbA1C values that do not accurately reflect mean glucose values.

31OCT03 NONE

ENZYMES			UNITS	REFERENCE
LDH	181		U/L	[94-250]

31OCT03 NONE

CARDIAC RISK INDICATORS			UNITS	REFERENCE
TRIG	116		MG/DL	[0-149]
CHOL	205	H	MG/DL	[0-199]
HDL CHOL	50		MG/DL	
CHOL/HDL	4.1	f	RATIO	
LDL CALC	132	H	MG/DL	[0-99]
LDL DIRECT	150	H	MG/DL	[0-99]

CHOL/HDL | LIPID ABNORMALITIES in ADULTS

	Desirable	Borderline Risk for CHD	High Risk for CHD
Cholesterol	(200	200 - 239	)=240
HDL Cholesterol	)= 60		(40
LDL Cholesterol	(130	130 - 159	)=160
	(100 optimal		
Cholesterol/HDL	(5	5 - 6	) 6
Triglceride	(150	150 - 199	) 200

This information is based on the Adult Treatment Panel III NCEP Guidelines for adults)= 20 years of age, for fasting specimens. LDL cholesterol ranges are based on direct measurement assays. LDL goals are further modified by clinical risk for CHD.
Ref: JAMA 2001;285:2486.

H-HIGH, f-FOOTNOTE

REQUESTING PHYSICIAN

11/03/03

ORDER MD:
CONSULT MD(s):
CONSULT MD(s):

Pull Chart	Review Complete
Initials	Initials
Date	Date

DRAW DATE / TIME

CHEMICAL PATHOLOGY

31OCT03 NONE

THYROID FUNCTION			UNITS	REFERENCE
HS TSH	2.85	f	IU/L	[0.35-5.50]
FREE T3	3.7		pg/ml	[2.3-4.2]
FREE T4	1.2	f	NG/DL	[0.8-1.8]

HS TSH

Guidelines for interpreting TSH values:
If the TSH result is HIGH; suggests HYPOTHYROIDISM.
IF THE TSH result is LOW; suggests HYPERTHYROIDISM.
Some patients with LOW TSH values are clinically HYPERTHYROID, while others are EUTHYROID.
Assays of FREE T4 and FREE T3 may be of value to confirm the diagnosis.
TSH results alone can be misleading in patients with hypothalamic or pituitary disorders, or in patients during the transitional phase of thyroid treatment.

FREE T4

Guidelines for interpreting FREE T4 values:
If the TSH result is HIGH and FT4 is LOW; suggests HYPOTHYROIDISM
If the TSH result IS HIGH and FT4 is NORMAL; suggests SUBCLINICAL HYPOTHYROIDISM.
If the TSH result is LOW and FT4 is HIGH; suggests HYPERTHYROIDISM
If the TSH result is LOW and FT4 is NORMAL; suggests SUBCLINICAL HYPERTHYROIDISM. A FREE T3 to rule out T3 THYROTOXICOSIS is also suggested.

These interpretations may not apply to patients with hypothalamic or pituitary disorders, or in patients on thyroid treatment.

ONCO-FETAL PROTEINS			UNITS	REFERENCE
PROS SP AG	1.13	f	NG/ML	[0.00-4.00]

PROS SP AG

PSA determined by the Bayer ACS:CENTAUR PSA Equimolar Assay

REQUESTING PHYSICIAN

11/03/03

ORDER MD:
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CONSULT MD(s):

Pull Chart	Review Complete
Initials	Initials
Date	Date

DRAW DATE / TIME

HEMATOPATHOLOGY

31OCT03 NONE

CELL COUNTS		UNITS	REFERENCE	DIFFERENTIAL	%	ABSOLUTE DIFF		UNITS	REFERENCE
WBC	7.2	K/UL	[4.3-10.0]	NEUTROPHIL	61	NEUTROPHIL	4.4	K/UL	[1.8-7.5]
HGB	15.8	GM/DL	[13.5-16.5]	LYMPHOCYTE	31	LYMPHOCYTE	2.2	K/UL	[0.8-4.5]
HCT	46.3	%	[40.0-50.0]	MONOCYTE	7	MONOCYTE	0.5	K/UL	[0.1-1.5]
MCV	90	FL	[80-98]	EOSINOPHIL	1	EOSINOPHIL	0.1	K/UL	[0.0-0.4]
RBC	5.13	M/UL	[4.40-5.80]	BASOPHIL	1	BASOPHIL	0.1	K/UL	[0.0-0.5]
MCH	30.9	PG	[27.0-34.0]						
MCHC	34.2	%	[32.0-36.0]						
RDW	12.6	%	[0.0-15.5]						
PLATELET	249	K/UL	[150-450]						

URINALYSIS

31OCT03 NONE

URINALYSIS		REFERENCE	MICROSCOPIC		CASTS/LPF
SPEC GRAV	1.012	[1.005-1.030]	WBC/HPF	5	
PH	7.0	[4.5-8.0]	RBC/HPF	0	
PROTEIN	NEG	[NEG]	BACTERIA	MANY	
GLUCOSE	NEG	[NEG]	SQ EPITH/LPF	(1	
KETONES	NEG	[NEG]			
BILIRUBIN	NEG	[NEG]			
BLOOD	NEG	[NEG]			
UROBILIN	0.2	[0.0-1.0]			
LEUK EST	SMALL *	[NEG]			
NITRITE	POS *	[NEG]			

Repeat UA

CHEMICAL PATHOLOGY

31OCT03 NONE

Hep ABC

		UNITS	REFERENCE			UNITS	REFERENCE
GLUCOSE	93	MG/DL	[65-110]	TOT BILI	.8	MG/DL	[.2-1.2]
NA	140	MMOL/L	[135-147]	SGOT/AST	53 H	U/L	[0-44]
K	4.3	MMOL/L	[3.5-5.5]	SPT/ALT	99 H	U/L	[0-44]
CL	106	MMOL/L	[96-108]	GAMMA GT	59 H	U/L	[11-49]
CO2	24	MMOL/L	[22-29]	ALK PHOS	89	U/L	[40-129]
ANION GAP	10	MMOL/L	[5-14]	URIC ACID	6.8	MG/DL	[3.4-7.0]
BUN	11	MG/DL	[6-20]	PHOS	3.0	MG/DL	[2.7-4.5]
CREA	1.0	MG/DL	[0.5-1.2]	CALCIUM	10.0	MG/DL	[8.4-10.5]
UREA/CREA	11	RATIO	[10-20]				
OSMO CALC	278	MOS/KG	[268-292]				
TOT PROTEIN	7.9	GM/DL	[6.6-8.7]				
ALBUMIN	4.7	GM/DL	[3.4-4.8]				
GLOBULIN	3.2	GM/DL	[2.4-4.4]				
A/G RATIO	1.5	RATIO	[0.7-2.5]				

MW 11/03 Rec'd

11/26/03

ORDER MD:
CONSULT MD(s):
CONSULT MD(s):

Pull Chart	Review Complete
Initials	Initials
Date	Date

VIRAL SEROLOGY

17NOV03 NONE

		REFERENCE
HEPATITIS TESTING		
HBS AG	NEG	[NEG]
HB CORE IGM	NEG	[NEG]
HEP A AB (IGM)	NEG	[NEG]
HEP C RNA @	POSITIVE*f	

HEP C RNA..... 17NOV03 NONE The specimen was POSITIVE for Hepatitis C Viral RNA.
HCV RNA was detected. This assay can detect down to
50 IU/mL (100 copies/mL). False positives can occur due
to contamination.
TEST INFORMATION: Hepatitis C RNA, Qual by PCR

Assay methodology is polymerase chain reaction (PCR)
using the FDA approved Roche Amplicor HCV Test,
version 2.0.

This test is performed pursuant to an agreement with
Roche Molecular Systems, Inc.
The above test was performed at:

mw 11-28-03 Refax to PD.

mw

*-ABNORMAL, f-FOOTNOTE
@ = HEP C RNA TEST SENT TO

****** FINAL REPORT ******

11/26/03

ORDER MD:
CONSULT MD(s):
CONSULT MD(s):

Pull Chart ____ Recvd Complete ____
Initials ____
Date ____

VIRAL SEROLOGY

17NOV03 NONE

HEPATITIS TESTING

		REFERENCE
	HEP C GENOTYPE @	TYPE 4f
HEP C GENOTYPE, 17NOV03	NONE	TYPE 4. Cannot be further subtyped.

TEST INFORMATION: Hepatitis C Genotyping
Isolates of Hepatitis C Virus are grouped into six major genotypes. These genotypes are subtyped according to sequence characteristics and are designated as 1a, 1b, 2a, 2b, 3a, 3b, 4a-h, 5a, and 6a.

Reports suggest that patient prognosis and disease course may be genotype dependent. For example, Hepatitis C Virus type 1 and type 4 infections may be associated with more severe disease and decreased responsiveness to therapy. In addition, types 2 and 3 may be treated with shorter durations of therapy.

Patient RNA is assayed using reverse transcription polymerase chain reaction (RT-PCR) to amplify a specific portion of the 5'untranslated region (5'UTR) of the hepatitis C virus. The amplified nucleic acid was sequenced bidirectionally using dye-terminator chemistry (ABI). Results are based on comparison with a database derived from GenBank sequences and published information (Maertens et al, 1997).

The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.
The above test was performed at:

****** FINAL REPORT ******

11/26/03

ORDER MD:
CONSULT MD(s):
CONSULT MD(s):

VIRAL SEROLOGY

17NOV03 NONE

			HEPATITIS TESTING	REFERENCE
			HCV AB	[NEG]
HCV AB.....	17NOV03	NONE	POS*f	

Follow up testing for Hepatitis C Virus RNA, QUALITATIVE (not quantitative) is recommended if clinically indicated. Patients with certain immunologic disorders (including but not limited to SLE, rheumatoid arthritis, hypergammaglobulinemia, and HIV-1 infection) may have a FALSE POSITIVE anti-HCV antibody test by the EIA method.

RESULTS REPORTED TO THE DEPARTMENT OF PUBLIC HEALTH.

*-ABNORMAL, f-FOOTNOTE

****** FINAL R E P O R T ******

CHEMICAL PATHOLOGY

	ONCO-FETAL PROTEINS		UNITS	REFERENCE
JAN04 1705				
	A-FETOPROT 3	f	NG/ML	[0-8]

FETOPROT

The above reference range is for non-pregnant adult patients. Pregnant patients should be processed through the STATE OF CALIFORNIA AFP SCREENING PROGRAM ONLY.

AFP ranges for neonates (premature or full-term, male or female) are significantly higher (several thousandfold) than the above reference range. It is not known precisely at what age AFP levels in infants drop to the adult range. Therefore serial serum AFP levels are recommended when evaluating patients less than one year of age.

AFP determined by the Bayer ACS: Centaur AFP assay.

VIRAL SEROLOGY

	HEPATITIS TESTING			REFERENCE
JAN04 1705				
	HEP A AB(TOTAL)	NEG		[NEG]
	HEP A AB(IGM)	*	f	[NEG]

› A AB(IGM).. 05JAN04 1705 * Hepatitis A total antibody screen (IgM & IgG) NEGATIVE. Hepatitis A IgM NOT indicated.

✓ J

Pull Chart	Review Complete
Initials	Initials
DATE: 01/10/04 Date	Date

OOTNOTE

ENT: *PT NO:* *LOCATION:*

****** FINAL REPORT ******

VIRAL SEROLOGY

HEPATITIS TESTING **REFERENCE**

05JAN04 1705

HEP C RNA @ 4.6 f log IU

HEP C RNA..... 05JAN04 1705 <><>VIRAL LOAD RESULT FOR HCV RNA IS 37,100 IU/ML<><>
THE LOG 10 VALUE OF HCV RNA IS 4.6
TEST INFORMATION: HEP C RNA Quant Real-Time PCR
Assay methodology is polymerase chain reaction (PCR) using the ROCHE COBAS TaqMan Analyte Specific Reagent.
The reference interval for this assay is:
Less than 2.3 log IU (200 IU) of HCV RNA/mL.
The analytic measurement range of this assay is:
200-100,000,000 IU/mL (2.3-8.0 Log IU/mL).

There is an approximate relationship of 1 HCV RNA IU/mL to 2.5 HCV RNA copies/mL. The INTERNATIONAL UNIT (IU) is a designated unit value assigned to the "International Standard for Nucleic Acid Amplification Technology Assays for HCV RNA" which is accepted by the WHO Expert Committee on Biological Standardization. The International Standard is a lyophilized preparation of HCV genotype 1. The IU value is based on results obtained after extensive testing in a variety of assay types.

Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration approval. This test was developed and its performance characteristics determined by ARUP Laboratories, Inc. It has not been approved by the U.S. Food and Drug Administration. This test should not be regarded as investigational or for research use.

This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.
The above test was performed at: Associated Regional and University Pathologists, 500 Chipeta Way, SLC UT 84108

1-16-04
Discussed c pt
Hep C test mod ⊕
Recommend liver
biopsy by
Radiologist

f-FOOTNOTE
@ = HEP C RNA TEST SENT TO

Pull Chart	Review Complete
Initials	Initials
Date	Date

PT NO: LOCATION:

****** FINAL REPORT ******

3-FEB-2004

Accession#:
Patient:
Collected: 01/30/04

Loc:
Pt#:
SS#:
DOB:

P A T H O L O G Y R E P O R T

SPECIMEN:

LIVER BIOPSY

GROSS DESCRIPTION:

Received in formalin, labeled US liver biopsy, and 1599, is a 2.0 x 0.1 cm tan, cylindrical portion of soft tissue. T1 in 1599.

CC:Jm

MICROSCOPIC DESCRIPTION:

Sections show a needle core of liver tissue. This shows at least ten portal areas for evaluation. There is a variable chronic inflammatory infiltrate in the portal areas with small lymphoid follicle formation. This pattern is compatible with the stated history of hepatitis C. There is focal interface activity with lymphocytes in many of the portal areas extending beyond the limiting plate. There appears to be some probable mild fibrous portal expansion, but no periportal fibrosis is identified. Bile ductules are present within the portal areas and do not show evidence of damage. Iron is not increased.

Notify

JK :am

OK to start Pegasys / Ribavirin 1200 mg

✓J

2/4/04 auth for meds submitted

Printed: 02/03/04
Page: 1

Continued on next page...

Accession#:
Patient:

PATHOLOGY REPORT

DIAGNOSIS:

LIVER, BIOPSY:

CHRONIC HEPATITIS DISPLAYING MILD INFLAMMATORY ACTIVITY (GRADE 2/4) AND MILD FIBROUS PORTAL EXPANSION (STAGE 1/4).

COMMENT: The patient is noted to have a history of hepatitis C.

Q: TG
JK :am 02/02/04

(Electronic Signature) Ver:JK 02/02/04

End of Report...

PRINTED: 03/16/04

HEMATOPATHOLOGY

	CELL COUNTS		UNITS	REFERENCE	DIFFERENTIAL	%	ABSOLUTE DIFF		UNITS	REFERENCE
15MAR04 1300										
	WBC	6.0	K/UL	[4.3-10.0]	NEUTROPHIL	70	NEUTROPHIL	4.2	K/UL	[1.8-7.5]
	HGB	**12.0L**	GM/DL	[13.5-16.5]	LYMPHOCYTE	21	LYMPHOCYTE	1.3	K/UL	[0.8-4.5]
	HCT	**34.7L**	%	[40.0-50.0]	MONOCYTE	9	MONOCYTE	0.5	K/UL	[0.1-1.5]
	MCV	89	FL	[80-98]	EOSINOPHIL	0	EOSINOPHIL	0.0	K/UL	[0.0-0.4]
	RBC	**3.91L**	M/UL	[4.40-5.80]	BASOPHIL	1	BASOPHIL	0.1	K/UL	[0.0-0.5]
	MCH	30.7	PG	[27.0-34.0]						
	MCHC	34.6	%	[32.0-36.0]						
	RDW	13.8	%	[0.0-15.5]						
	PLATELET	199	K/UL	[150-450]						

3/17/04
D/C'd c pt

VJ

Pull Chart	Review Complete
Initials	Initials
Date	Date

PT NO: *LOCATION:*

****** FINAL REPORT ******

PATIENT:
PT NO:
SEX:
AGE:
DOB:
ADMITTING MD:
ORDERING MD:
CONSULTING MD:

Date of Service: 04/12/2004 02:04 PM

FINAL REPORT

Test	Value		Units	Range	Remark
OBTAINED: 04/12/2004 09:10 AM				**REPORTED:** 04/12/2004 05:00 PM	
***** HEPATIC FUNCTN *****					
SGOT/AST		21 (was 63 - 99)	U/L	0-44	
GPT/ALT		32	U/L	0-44	
ALK PHOS		86	U/L	40-129	
TOT PROTEIN		6.9	GM/DL	6.3-8.3	
ALBUMIN		4.0	GM/DL	3.6-5.0	
TOT BILI		.6	MG/DL	.2-1.2	
CONJ BILI		.1	MG/DL	.0-.3	
GLOBULIN		2.9	GM/DL	2.4-4.4	
A/G RATIO		1.4	RATIO	0.7-2.5	
***** CBC *****					
WBC	**3.9**		**K/UL**	**4.3-10.0**	**LOW**
RBC	**3.82**		**M/UL**	**4.40-5.80**	**LOW**
HGB	**11.7**		**GM/DL**	**13.5-16.5**	**LOW**
HCT	**35.6**		**%**	**40.0-50.0**	**LOW**
MCV		93	FL	80-98	
MCH		30.8	PG	27.0-34.0	
MCHC		32.9	%	32.0-36.0	
RDW	**17.9**		**%**	**0.0-15.5**	**HIGH**
PLATELET		180	K/UL	150-450	
MPV	**11.5**			**8.2-10.0**	**HIGH**
NEUTROPHIL		67	%		
LYMPHOCYTE		25	%		
MONOCYTE		8	%		
EOSINOPHIL		0	%		
BASOPHIL		0	%		
NEUTROPHIL		2.6	K/UL	1.8-7.5	
LYMPHOCYTE		1.0	K/UL	0.8-4.5	
MONOCYTE		0.3	K/UL	0.1-1.5	
EOSINOPHIL		0.0	K/UL	0.0-0.4	
BASOPHIL		0.0	K/UL	0.0-0.5	

Reviewed by:

Labs OK - liver tests better (Normal)

On Pegasys / Ribavirin x 1 mo

VJ

04/13/2004

4-14-04 pt notified

RD

PATIENT:
PT NO:
SEX:
AGE:
DOB:
ORDER MD:
CONSULT MD(s):
CONSULT MD(s):

ROUTE TO:

REFERRING MEDICAL RECORD NUMBER:
DIAGNOSIS:

PRINTED: 05/12/04

HEMATOPATHOLOGY

	CELL COUNTS		UNITS	REFERENCE	DIFFERENTIAL	%	ABSOLUTE DIFF		UNITS	REFERENCE
11MAY04 1520										
	WBC	**2.9L**	K/UL	[4.3-10.0]	NEUTROPHIL	55	NEUTROPHIL	**1.6** L	K/UL	[1.8-7.5]
	HGB	**11.2L**	GM/DL	[13.5-16.5]	LYMPHOCYTE	33	LYMPHOCYTE	1.0	K/UL	[0.8-4.5]
	HCT	**33.3L**	%	[40.0-50.0]	MONOCYTE	11	MONOCYTE	0.3	K/UL	[0.1-1.5]
	MCV	93	FL	[80-98]	EOSINOPHIL	0	EOSINOPHIL	0.0	K/UL	[0.0-0.4]
	RBC	**3.57L**	M/UL	[4.40-5.80]	BASOPHIL	1	BASOPHIL	0.0	K/UL	[0.0-0.5]
	MCH	31.5	PG	[27.0-34.0]						
	MCHC	33.8	%	[32.0-36.0]						
	RDW	**16.0H**	%	[0.0-15.5]						
	PLATELET	189	K/UL	[150-450]						

CHEMICAL PATHOLOGY

			UNITS	REFERENCE			UNITS	REFERENCE
11MAY04 1520								
	TOT PROTEIN	7.1	GM/DL	[6.3-8.3]	TOT BILI	.7	MG/DL	[.2-1.2]
	ALBUMIN	4.1	GM/DL	[3.6-5.0]	CONJ BILI	.1	MG/DL	[.0-.3]
	GLOBULIN	3.0	GM/DL	[2.4-4.4]	SGOT/AST	24	U/L	[0-44]
	A/G RATIO	1.4	RATIO	[0.7-2.5]	GPT/ALT	31	U/L	[0-44]
					ALK PHOS	87	U/L	[40-129]

	THYROID FUNCTION			UNITS	REFERENCE
11MAY04 1520					
	HS TSH	1.33	f	IU/L	[0.35-5.50]

HS TSH

Guidelines for interpreting TSH values:
If the TSH result is HIGH; suggests HYPOTHYROIDISM.
IF THE TSH result is LOW; suggests HYPERTHYROIDISM.
Some patients with LOW TSH values are clinically HYPERTHYROID, while others are EUTHYROID.
Assays of FREE T4 and FREE T3 may be of value to confirm the diagnosis.
TSH results alone can be misleading in patients with hypothalamic or pituitary disorders, or in patients during the transitional phase of thyroid treatment.

L-LOW, H-HIGH, f-FOOTNOTE

Pull Chart	Review Complete
Initials	Initials
Date	Date

PT NO: *LOCATION:*

****** FINAL REPORT ******

DRY DATE: 05/19/04
TIME: 1421
PAGE: 1

DIAGNOSIS:

CONSULT MD(s):
CONSULT MD(s):

Notify

+++++ VIRAL SEROLOGY +++++

11MAY04 1520

HEPATITIS TESTING

HCV RNA BDNA	<3200 f	COPIES
HCV RNA LOG CPY	<3.5	LOG
HCV RNA IU	<615	IU/ML
HCV RNA LOG I.	<2.8	LOG IU

HCV RNA Neg

Good

Liver tests WNL

Cont Rx

HCV RNA BDNA

ANALYTICAL RANGE of the HCV RNA assay:

Copies/ml: 3,200 to 40,000,000
Log Copies: 3.5 to 7.6
IU/ml: 615 to 7,692,308
Log IU: 2.8 to 6.9

The International Unit (IU) is a unit value assigned to the "First International Standard for Nucleic Acid Amplification Technology Assays for HCV RNA" accepted by the WHO Expert Committee on Biological Standardization. The International Standard is a preparation of HCV genotype 1 and is based on results obtained in a variety of assay types.

The quantitative HCV RNA assay is intended for use in patients with an established diagnosis of Hepatitis C. It should NOT be used as a diagnostic test. Results less than the limit of detectability do not imply either the presence or absence of virus.

This patient's result was obtained using the Bayer Diagnostics (Versant) branched-DNA HCV RNA methodology, version 3.0. The U.S. Food and Drug Administration has approved this assay for the quantitation of Hepatitis C viral RNA in the serum or plasma of HCV infected individuals.

f-FOOTNOTE

END OF REPORT

✓J

Notified Patient
Date: 5-19-04

PATIENT:
PT NO:
SEX:
AGE:
DOB:
ADMITTING MD:
ORDERING MD:
CONSULTING MD:

Date of Service: 06/17/2004 12:29 AM

FINAL REPORT JUN 1 8 2004

Test	Value		Units	Range	Remark
OBTAINED: 06/16/2004 12:01 AM				**REPORTED:** 06/17/2004 08:40 AM	
*** **CBC** ***					
WBC	**3.9**		**K/UL**	**4.3-10.0**	**LOW**
RBC	**3.54**		**M/UL**	**4.40-5.80**	**LOW**
HGB	**11.1**		**GM/DL**	**13.5-16.5**	**LOW**
HCT	**33.7**		**%**	**40.0-50.0**	**LOW**
MCV		95	FL	80-98	
MCH		31.4	PG	27.0-34.0	
MCHC		33.0	%	32.0-36.0	
RDW	**15.6**		**%**	**0.0-15.5**	**HIGH**
PLATELET		210	K/UL	150-450	
MPV	**10.6**			**8.2-10.0**	**HIGH**
NEUTROPHIL		69	%		
LYMPHOCYTE		20	%		
MONOCYTE		11	%		
EOSINOPHIL		0	%		
BASOPHIL		0	%		
NEUTROPHIL		2.7	K/UL	1.8-7.5	
LYMPHOCYTE		0.8	K/UL	0.8-4.5	
MONOCYTE		0.4	K/UL	0.1-1.5	
EOSINOPHIL		0.0	K/UL	0.0-0.4	
BASOPHIL		0.0	K/UL	0.0-0.5	

Reviewed by:

CBC OK Notify

✓

Notified Patient by v-mail
Date: 6-18-04 mm

6/18/2004

PATIENT:
PT NO:
SEX: **Date of Service:** 08/16/2004 07:40 PM
AGE:
DOB:
ADMITTING MD:
ORDERING MD: FINAL REPORT
CONSULTING MD:

Test	Value		Units	Range	Remark
OBTAINED: 08/16/2004 04:30 PM				**REPORTED:** 08/18/2004 01:31 PM	
***** HEPATIC FUNCTN *****					
SGOT/AST		26	U/L	0-44	
GPT/ALT		29	U/L	0-44	
ALK PHOS		84	U/L	40-129	
TOT PROTEIN		8.0	GM/DL	6.3-8.3	
ALBUMIN		4.2	GM/DL	3.6-5.0	
TOT BILI		.5	MG/DL	.2-1.2	
CONJ BILI		.1	MG/DL	.0-.3	
GLOBULIN		3.8	GM/DL	2.4-4.4	
A/G RATIO		1.1	RATIO	0.7-2.5	
***** CBC *****					
WBC		5.3	K/UL	4.3-10.0	
RBC	**3.64**		**M/UL**	**4.40-5.80**	**LOW**
HGB	**11.5**		**GM/DL**	**13.5-16.5**	**LOW**
HCT	**34.5**		**%**	**40.0-50.0**	**LOW**
MCV		95	FL	80-98	
MCH		31.6	PG	27.0-34.0	
MCHC		33.2	%	32.0-36.0	
RDW		14.9	%	0.0-15.5	
PLATELET		228	K/UL	150-450	
MPV	**11.5**			**8.2-10.0**	**HIGH**
NEUTROPHIL		76	%		
LYMPHOCYTE		14	%		
MONOCYTE		10	%		
EOSINOPHIL		0	%		
BASOPHIL		0	%		
NEUTROPHIL		4.0	K/UL	1.8-7.5	
LYMPHOCYTE	**0.7**		**K/UL**	**0.8-4.5**	**LOW**
MONOCYTE		0.5	K/UL	0.1-1.5	
EOSINOPHIL		0.0	K/UL	0.0-0.4	
BASOPHIL		0.0	K/UL	0.0-0.5	
***** HEP C bDNA *****					
HCV RNA BDNA		<3200	COPIES		

Notify

Hep C tests ⊖ Good
OK to stop Pegasys/Ribavirin
Repeat same tests in 3 mo.

ANALYTICAL RANGE of the HCV RNA assay:

Copies/ml: 3,200 to 40,000,000
Log Copies: 3.5 to 7.6
IU/ml: 615 to 7,692,308
Log IU: 2.8 to 6.9

The International Unit (IU) is a unit value assigned to the "First

8-23-04 pt notified needs lab requisition

8/18/2004

International Standard for Nucleic Acid Amplification Technology Assays for HCV RNA" accepted by the WHO Expert Committee on Biological Standardization. The International Standard is a preparation of HCV genotype 1 and is based on results obtained in a variety of assay types.

The quantitative HCV RNA assay is intended for use in patients with an established diagnosis of Hepatitis C. It should NOT be used as a diagnostic test. Results less than the limit of detectability do not imply either the presence or absence of virus.

This patient's result was obtained using the Bayer Diagnostics (Versant) branched-DNA HCV RNA methodology, version 3.0. The U.S. Food and Drug Administration has approved this assay for the quantitation of Hepatitis C viral RNA in the serum or plasma of HCV infected individuals.

HCV RNA LOG CPY	<3.5	LOG
HCV RNA IU	<615	IU/ML
HCV RNA LOG IU	<2.8	LOG IU

Reviewed by:

PATIENT:
PT NO:
SEX:
AGE:
DOB:
ADMITTING MD:
ORDERING MD:
CONSULTING MD:

Date of Service: 11/29/2004 10:15 P

FINAL REPORT

DEC 0 2 2004

Test	Value	Units	Range	Remark
ACCESSION:	**OBTAINED:** 11/29/2004 04:50 PM		**REPORTED:** 12/01/2004 01:11 PI	
***** HEPATIC FUNCTN *****				
SGOT/AST	23	U/L	0-44	
GPT/ALT	21	U/L	0-44	
ALK PHOS	57	U/L	40-129	
TOT PROTEIN	7.4	GM/DL	6.3-8.3	
ALBUMIN	4.5	GM/DL	3.6-5.0	
TOT BILI	.4	MG/DL	.2-1.2	
CONJ BILI	.1	MG/DL	.0-.3	
GLOBULIN	2.9	GM/DL	2.4-4.4	
A/G RATIO	1.6	RATIO	0.7-2.5	
***** CBC *****				
WBC	7.4	K/UL	4.3-10.0	
RBC	5.17	M/UL	4.40-5.80	
HGB	15.9	GM/DL	13.5-16.5	
HCT	45.6	%	40.0-50.0	
MCV	88	FL	80-98	
MCH	30.7	PG	27.0-34.0	
MCHC	34.8	%	32.0-36.0	
RDW	13.5	%	0.0-15.5	
PLATELET	206	K/UL	150-450	
MPV	9.3		8.2-10.0	
NEUTROPHIL	61	%		
LYMPHOCYTE	30	%		
MONOCYTE	8	%		
EOSINOPHIL	1	%		
BASOPHIL	0	%		
NEUTROPHIL	4.5	K/UL	1.8-7.5	
LYMPHOCYTE	2.2	K/UL	0.8-4.5	
MONOCYTE	0.6	K/UL	0.1-1.5	
EOSINOPHIL	0.1	K/UL	0.0-0.4	
BASOPHIL	0.0	K/UL	0.0-0.5	
***** HEP C bDNA *****				
HCV RNA BDNA	<3200	COPIES		

ANALYTICAL RANGE of the HCV RNA assay:

Copies/ml: 3,200 to 40,000,000
Log Copies: 3.5 to 7.6
IU/ml: 615 to 7,692,308
Log IU: 2.8 to 6.9

The International Unit (IU) is a unit value assigned to the "First

Notify
Good results

Liver tests Normal

Hep C test Non active now

Ok to stop Pegasys / Rebavirin

Notified Patient
Date: 12/3/04 9:45 am
Mailed pt. labslip.

Repeat these labs in 12 wks

12/2/04 @ 2:58

12/1/2004

International Standard for Nucleic Acid Amplification Technology Assays for HCV RNA" accepted by the WHO Expert Committee on Biological Standardization. The International Standard is a preparation of HCV genotype 1 and is based on results obtained in a variety of assay types.

The quantitative HCV RNA assay is intended for use in patients with an established diagnosis of Hepatitis C. It should NOT be used as a diagnostic test. Results less than the limit of detectability do not imply either the presence or absence of virus.

This patient's result was obtained using the Bayer Diagnostics (Versant) branched-DNA HCV RNA methodology, version 3.0. The U.S. Food and Drug Administration has approved this assay for the quantitation of Hepatitis C viral RNA in the serum or plasma of HCV infected individuals.

HCV RNA LOG CPY	<3.5	LOG
HCV RNA IU	<615	IU/ML
HCV RNA LOG IU	<2.8	LOG IU

Reviewed by:

PATIENT:
PT NO:
SEX:
AGE:
DOB:
ADMITTING MD:
ORDERING MD:
CONSULTING MD:

Date of Service: 03/01/2005 05:22 P

FINAL REPORT

Test	Value	Units	Range	Remark
ACCESSION:	**OBTAINED:** 03/01/2005 03:00 PM		**REPORTED:** 03/04/2005 11:46 A	
***** HEPATIC FUNCTN *****				
SGOT/AST	24	U/L	0-44	
GPT/ALT	25	U/L	0-44	
ALK PHOS	59	U/L	40-129	
TOT PROT	7.8	GM/DL	6.3-8.3	
ALBUMIN	4.6	GM/DL	3.6-5.0	
TOT BILI	.6	MG/DL	.2-1.2	
CONJ BILI	.1	MG/DL	.0-.3	
GLOBULIN	3.2	GM/DL	2.4-4.4	
A/G RATIO	1.4	RATIO	0.7-2.5	
***** CBC *****				
WBC	7.9	K/UL	4.3-10.0	
RBC	4.90	M/UL	4.40-5.80	
HGB	15.0	GM/DL	13.5-16.5	
HCT	43.6	%	40.0-50.0	
MCV	89	FL	80-98	
MCH	30.6	PG	27.0-34.0	
MCHC	34.4	%	32.0-36.0	
RDW	13.1	%	0.0-15.5	
PLATELET	236	K/UL	150-450	
MPV	10.0		8.2-10.0	
NEUTROPHIL	68	%		
LYMPHOCYTE	23	%		
MONOCYTE	8	%		
EOSINOPHIL	1	%		
BASOPHIL	1	%		
NEUTROPHIL	5.4	K/UL	1.8-7.5	
LYMPHOCYTE	1.8	K/UL	0.8-4.5	
MONOCYTE	0.6	K/UL	0.1-1.5	
EOSINOPHIL	0.1	K/UL	0.0-0.4	
BASOPHIL	0.1	K/UL	0.0-0.5	
***** HEP C bDNA *****				
HCV RNA BDNA	<3200	COPIES		

ANALYTICAL RANGE of the HCV RNA assay:

Copies/ml: 3,200 to 40,000,000
Log Copies: 3.5 to 7.6
IU/ml: 615 to 7,692,308
Log IU: 2.8 to 6.9

The International Unit (IU) is a unit value assigned to the "First

Notified Patient
Date: 3/8/05 @ 9:35am

03-07-05, 12:55pm c/m for pt. to c/b

3/7/2005

|International Standard for Nucleic Acid Amplification Technology
|Assays for HCV RNA" accepted by the WHO Expert Committee on
|Biological Standardization. The International Standard is a
|preparation of HCV genotype 1 and is based on results obtained in a
|variety of assay types.
|
|The quantitative HCV RNA assay is intended for use in patients with
|an established diagnosis of Hepatitis C. It should NOT be used as
|a diagnostic test. Results less than the limit of detectability
|do not imply either the presence or absence of virus.
|
|This patient's result was obtained using the Bayer Diagnostics
|(Versant) branched-DNA HCV RNA methodology, version 3.0. The U.S.
|Food and Drug Administration has approved this assay for the
|quantitation of Hepatitis C viral RNA in the serum or plasma of HCV
|infected individuals.

HCV RNA LOG CPY	<3.5	LOG
HCV RNA IU	<615	IU/ML
HCV RNA LOG IU	<2.8	LOG IU

Reviewed by:

DATA TABULATIONS

I. **Hepatic Tumor Markers**
II. **Complete Blood Count with Differential Leukocytes**
III. **Comprehensive Metabolic Panel**
IV. **Hepatitis C Viral Load**

Table I. Hepatic Tumor Markers

Test	Day	Result		
		Low	Normal	High
Alpha Fetoprotein (0.0-5.5 ng/mL)	95		3	

Table II.

Complete Blood Count with Differential Leukocytes

Test	Day	Result		
		Low	Normal	High
White Blood Cells	27		7.2	
(WBC)	160		6.0	
	187	3.9		
(4.0-10.5 10^3/µL)	217	2.9		
	253	3.9		
	313		5.3	
	418		7.4	
	514		7.9	
Red Blood Cells	27		5.13	
(RBC)	160	3.91		
	187	3.82		
(4.38-5.62 10^6/µL)	217	3.57		
	253	3.54		
	313	3.64		
	418		5.17	
	514		4.90	
Hemoglobin	27		15.8	
	160	12.0		
(13.5-16.9 g/dL)	187	11.7		
	217	11.2		
	253	11.1		
	313	11.5		
	418		15.9	
	514		15.0	

Table II. Complete Blood Count (Cont'd.)

Test	Day	Result		
		Low	Normal	High
Hematocrit	27		46.3	
	160	34.7		
(39.5-50.0%)	187	35.6		
	217	33.3		
	253	33.7		
	313	34.5		
	418		45.6	
	514		43.6	
Mean Corpuscular Volume (MCV)	27		90	
	160		89	
	187		93	
(81.5-97.0 fL)	217		93	
	253		95	
	313		95	
	418		88	
	514		89	
Mean Corpuscular Hemoglobin (MCH)	27		30.9	
	160		30.7	
	187		30.8	
(27.0-33.5 pg)	217		31.5	
	253		31.4	
	313		31.6	
	418		30.7	
	514		30.6	
Mean Corpuscular Hemoglobin Concen-tration (MCHC)	27		34.2	
	160		34.6	
	187		32.9	
	217		33.8	
(32.0-35.5 g/dL)	253		33.0	
	313		33.2	
	418		34.8	
	514		34.4	

Table II. Complete Blood Count (Cont'd.)

Test	Day	Result		
		Low	Normal	High
Red Blood Cell Distribution Width (RDW)	27		12.6	
	160		13.8	
	187			17.9
(11.5-14.5%)	217			16.0
	253			15.6
	313			14.9
	418		13.5	
	514		13.1	
Platelets	27		249	
	160		199	
(150-400 $10^3/\mu L$)	187		180	
	217		189	
	253		210	
	313		228	
	418		206	
	514		236	
Neutrophils	27		4.4	
	160		4.2	
(2.0-8.1 $10^3/\mu L$)	187		2.6	
	217	1.6		
	253		2.7	
	313		4.0	
	418		4.5	
	514		4.4	
Lymphocytes	27		2.2	
	160		1.3	
(0.9-3.3 $10^3/\mu L$)	187		1.0	
	217		1.0	
	253	0.8		
	313	0.7		
	418		2.2	
	514		1.8	

Table II. Complete Blood Count (Cont'd.)

Test	Day	Result		
		Low	Normal	High
Monocytes	27		0.5	
	160		0.5	
(0.0-0.8 $10^3/\mu L$)	187		0.3	
	217		0.3	
	253		0.4	
	313		0.5	
	418		0.6	
	514		0.6	
Eosinophils	27		0.1	
	160		0.0	
(0.0-0.5 $10^3/\mu L$)	187		0.0	
	217		0.0	
	253		0.0	
	313		0.0	
	418		0.1	
	514		0.1	
Basophils	27		0.1	
	160		0.1	
(0.0-0.2 $10^3/\mu L$)	187		0.0	
	217		0.0	
	253		0.0	
	313		0.0	
	418		0.0	
	514		0.1	

Table III.

Comprehensive Metabolic Panel

Test	Day	Result		
		Low	Normal	High
Sodium (Serum) (135-145 meq/L)	27		140	
Potassium (Serum) (3.3-4.8 meq/L)	27		4.3	
Chlorides (Serum) (101-111 meq/L)	27		106	
Carbon Dioxide (25-34 meq/L)	27	24		
Electrolyte Balance (2-12 meq/L)	27		10	
Glucose (70-115 mg/dL)	1 27	43	 93	
Urea Nitrogen (8-26 mg/dL)	1 27		14 11	
Creatinine (0.5-1.3 mg/dL	1 27		1.0 1.0	

Table III.

Comprehensive Metabolic Panel (Cont'd.)

Test	Day	Result		
		Low	Normal	High
Calcium (8.4-10.2 mg/dL)	27		10.0	
Protein (Total) (6.1-8.2 g/dL)	1 27 187 217		8.0 7.9 6.9 7.1	
Albumin (3.2-5.5 g/dL	1 27 187 217		4.6 4.7 4.0 4.1	
Alkaline Phosphatase (26-110 IU/L)	1 27 187 217		71 69 86 87	
Aspartate Aminotrans-ferase/Serum Glutamic Oxaloacetic Trans-Aminase (AST/SGOT) (8-40 IU/L)	1 27 187 217		21 24	59 53
Alanine Aminotransferase/ Serum Glutamic-Pyruvic Transaminase (ALT/SGPT) (0-60 IU/L)	1 27 187 217		32 31	113 99

Table III.

Comprehensive Metabolic Panel (Cont'd.)

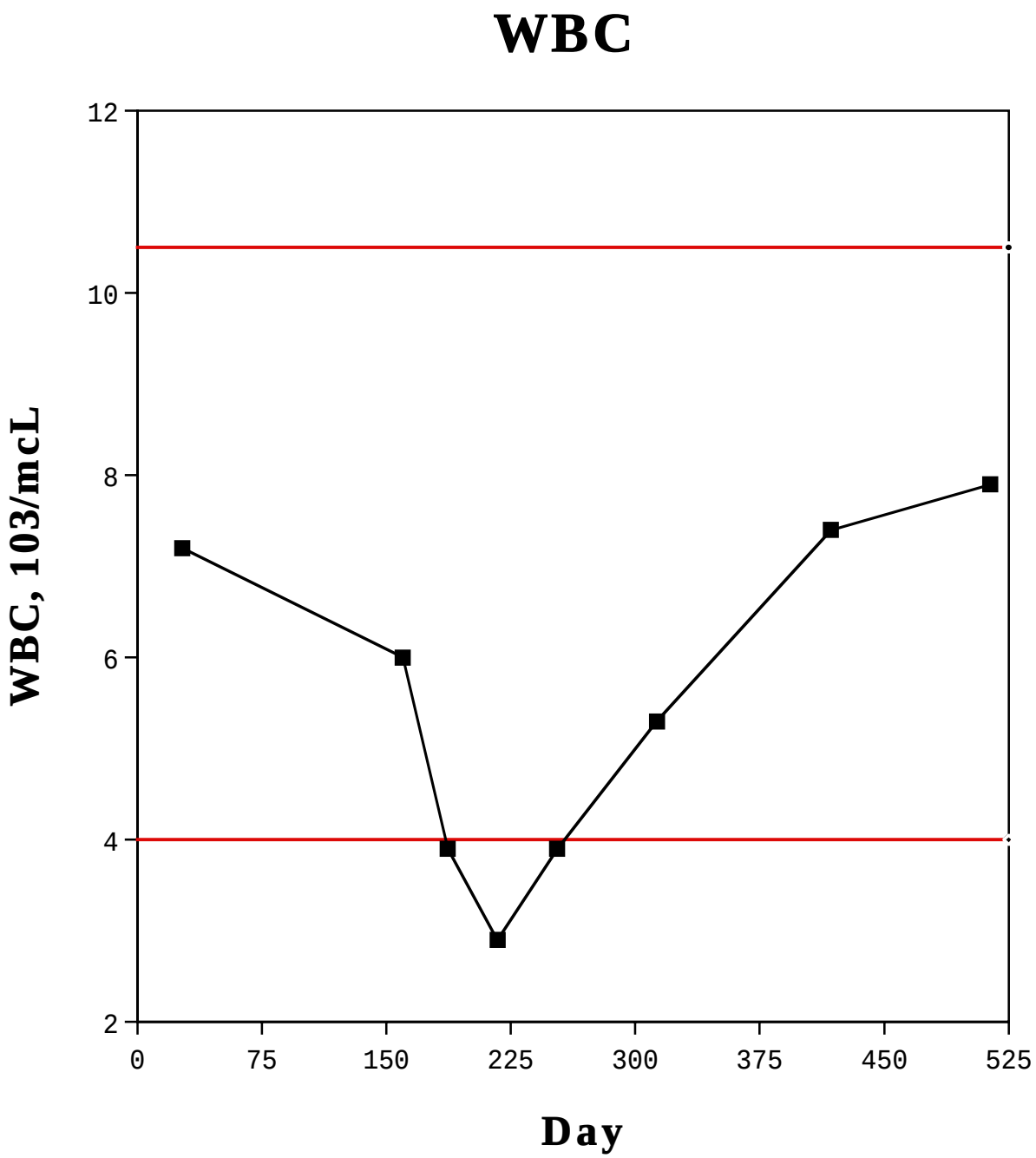
Test	Day	Result		
		Low	Normal	High
Bilirubin (Total)	1		0.8	
	27		0.8	
(0.0-1.4 mg/dL)	187		0.6	
	217		0.7	

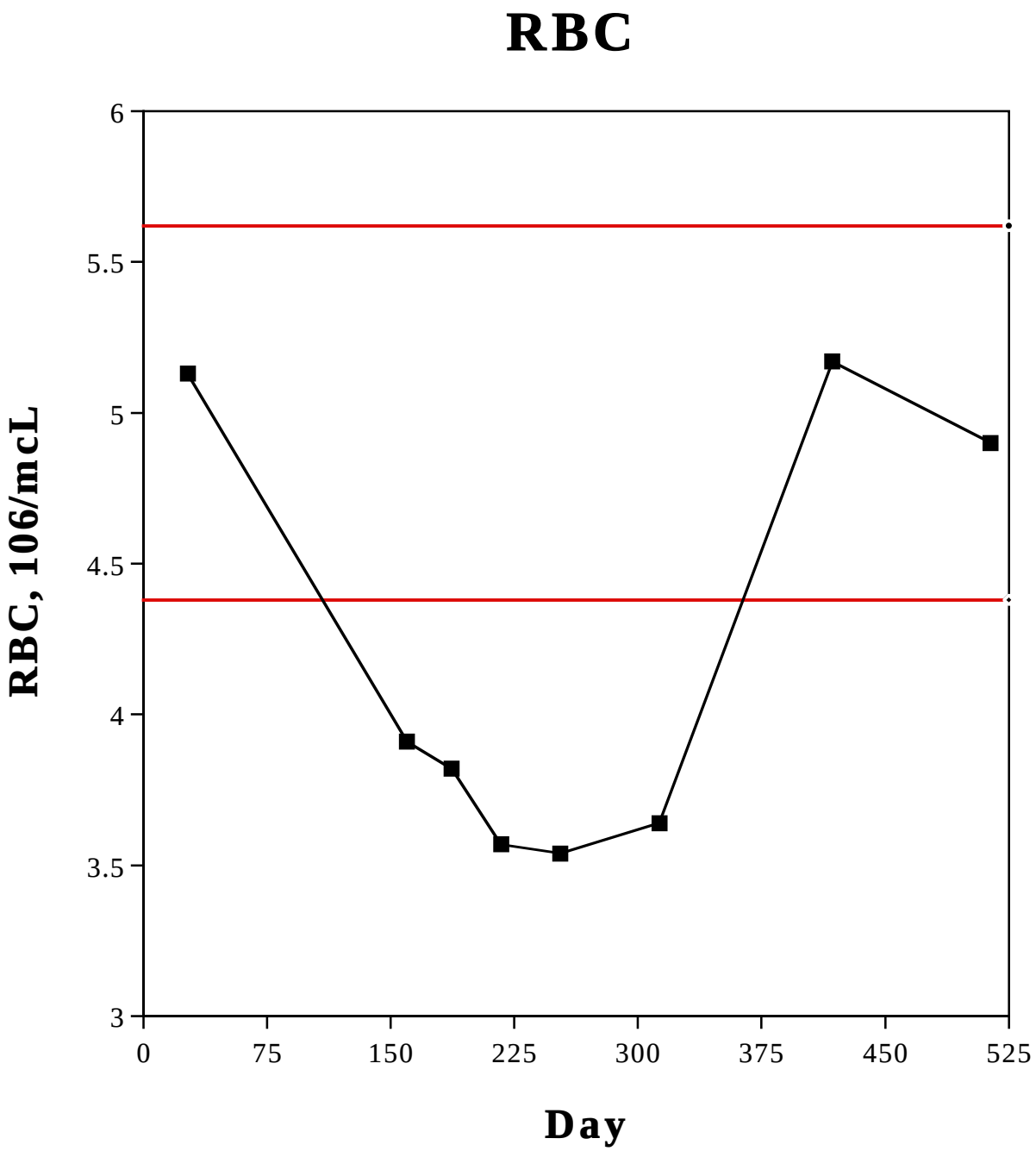
Table IV. Hepatitis C Viral Load

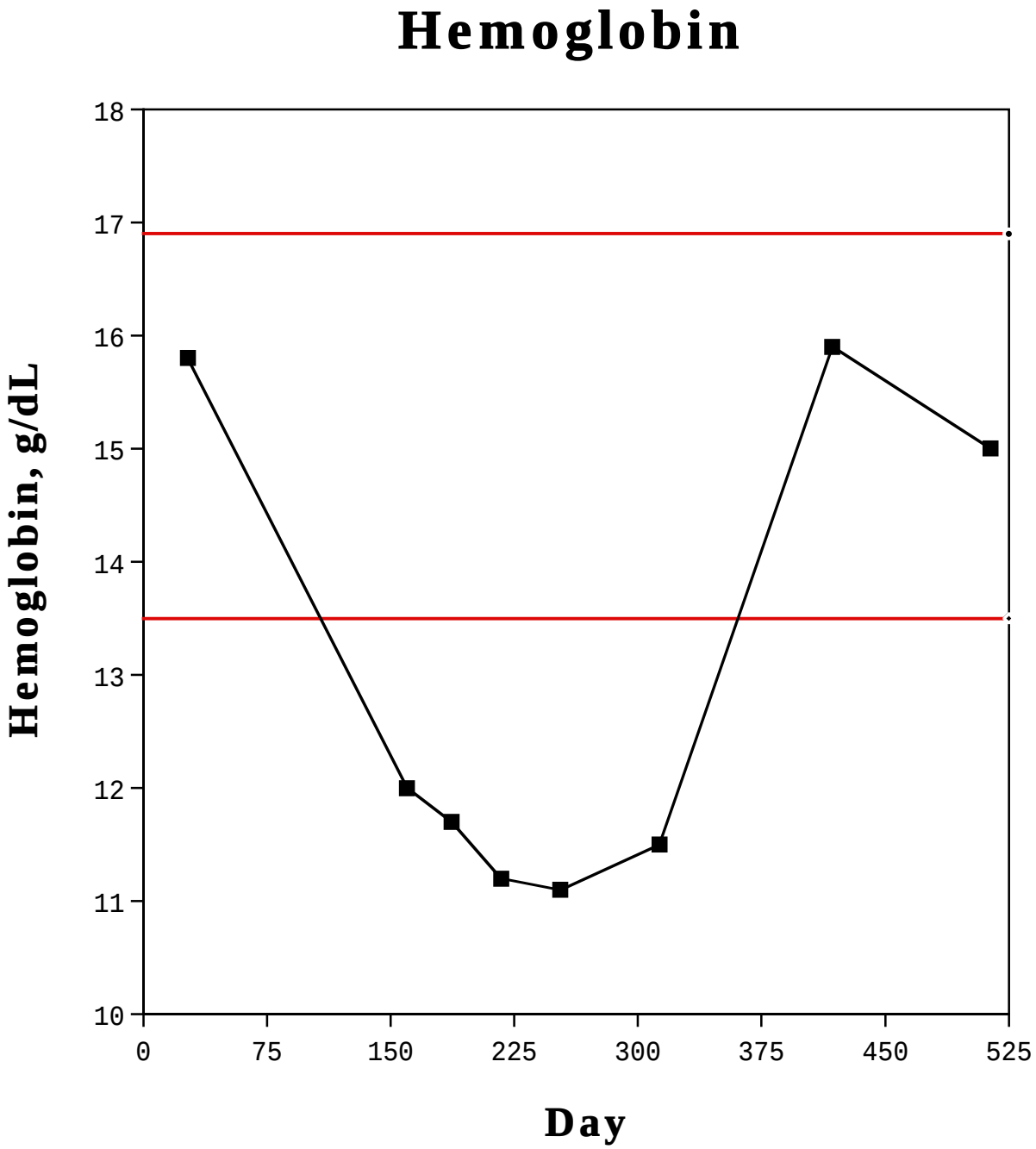
Test	Day	Result		
		Low	Normal	High
Hepatitis C Viral Load	1			pos.
(HCV–PCR Quant)	27			pos.
	50			pos.
(0 IU/mL)	95			37,100
	224		neg.	
	313		neg.	
	418		neg.	
	514		neg.	

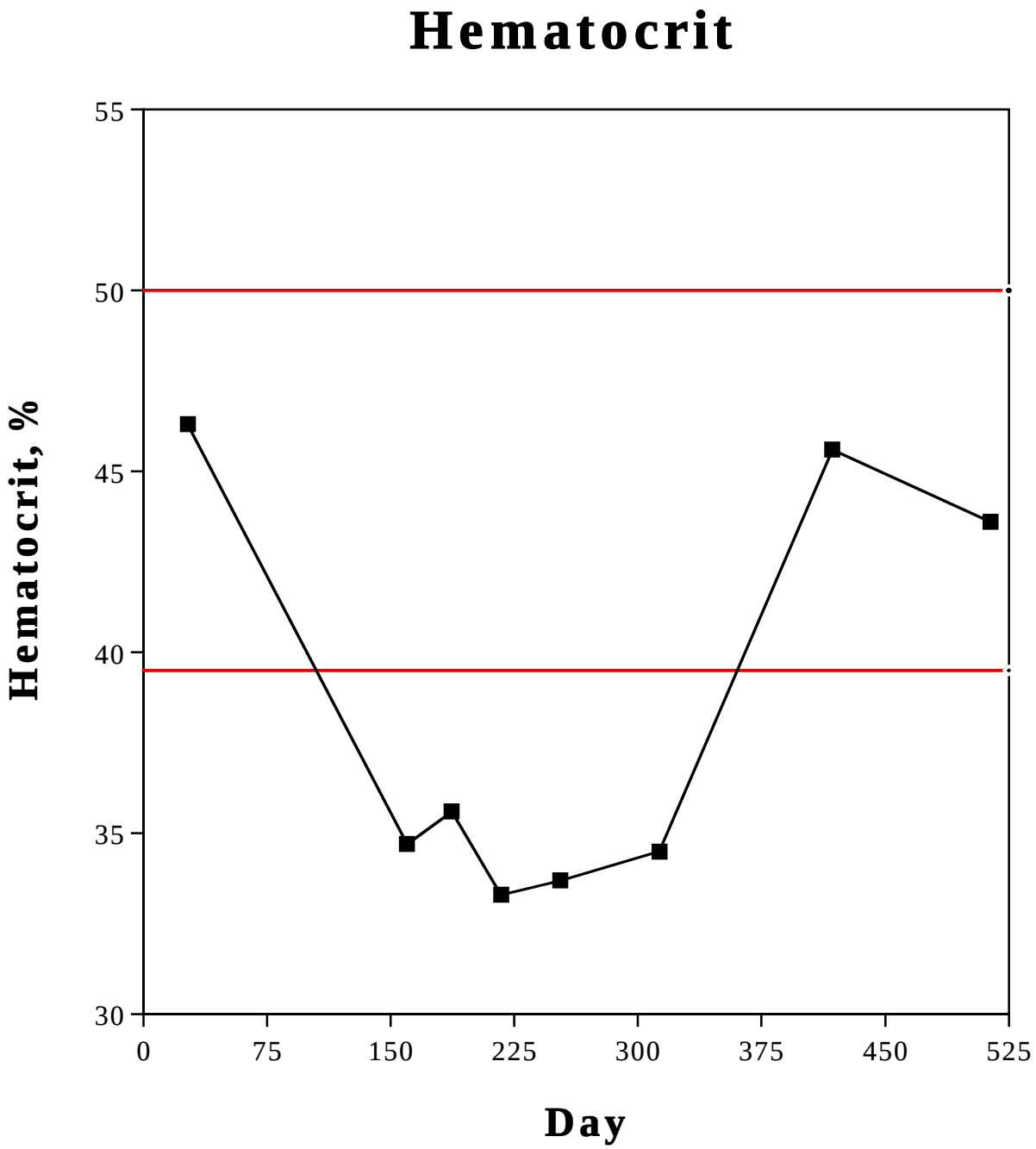
GRAPHICAL PRESENTATION OF SIGNIFICANT DATA

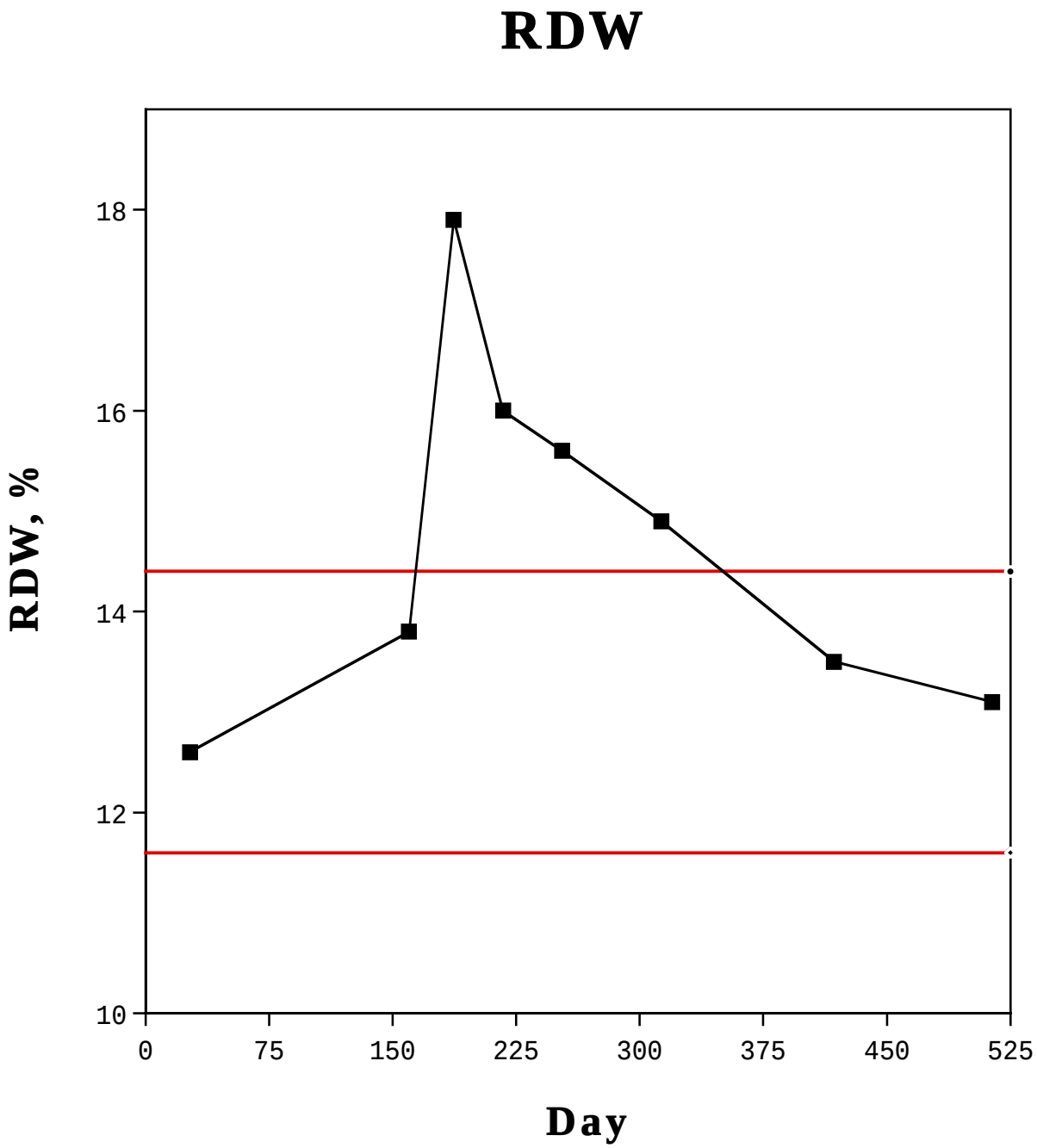
1. **Complete Blood Count: White Blood Cells (WBC)**
2. **Complete Blood Count: Red Blood Cells (RBC)**
3. **Complete Blood Count: Hemoglobin**
4. **Complete Blood Count: Hematocrit**
5. **Complete Blood Count: Red Blood Cell Distribution Width (RDW)**
6. **Comprehensive Metabolic Profile: ALT/SGPT**
7. **Comprehensive Metabolic Profile: AST/SGOT**
8. **Hepatitis C Viral Load**

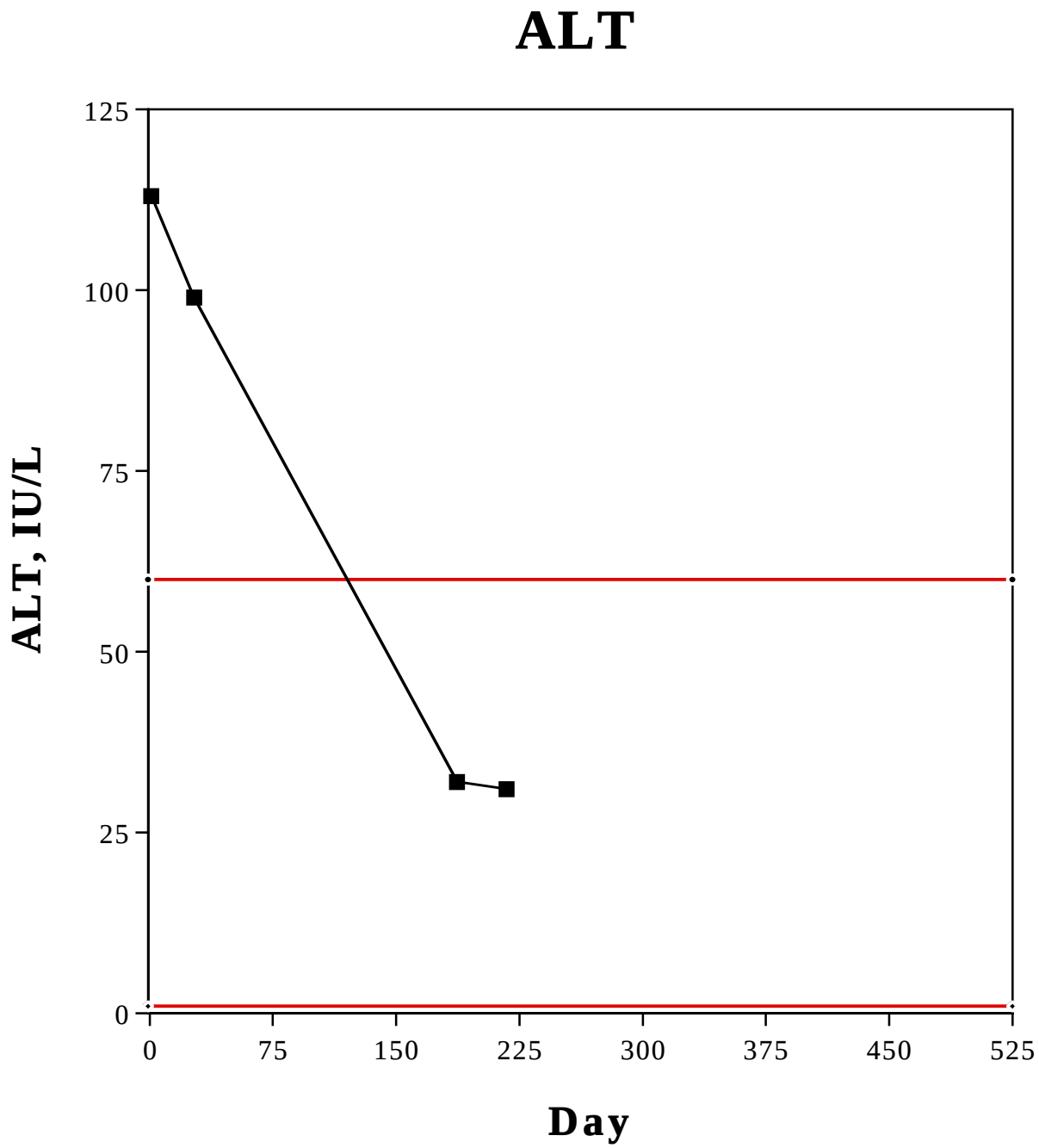

WBC
WBC, 103/mcL
12
10
8
6
4
2
0
75
150
225
300
375
450
525
Day

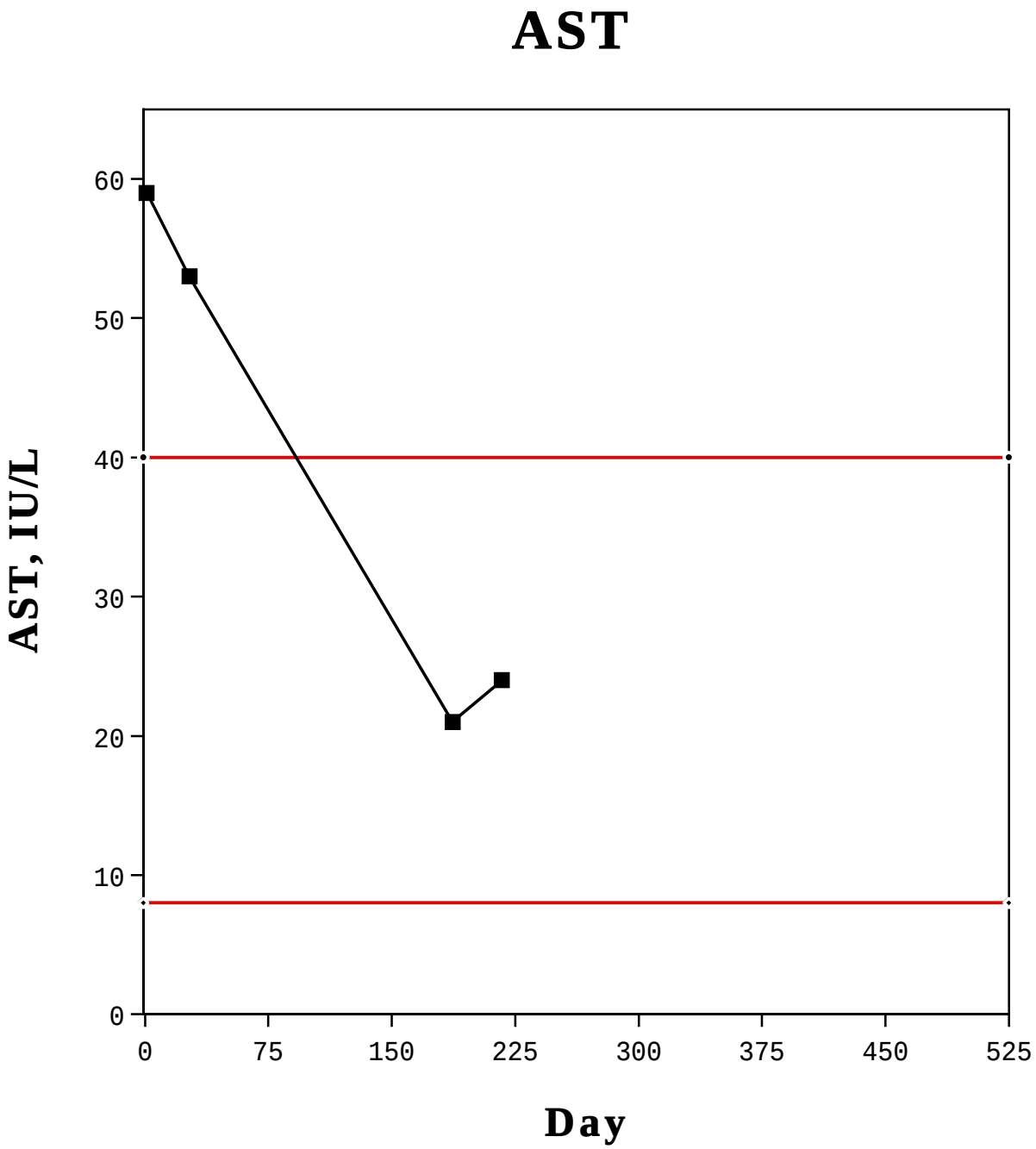

RBC
RBC, 106/mcL
6
5.5
5
4.5
4
3.5
3
0
75
150
225
300
375
450
525
Day

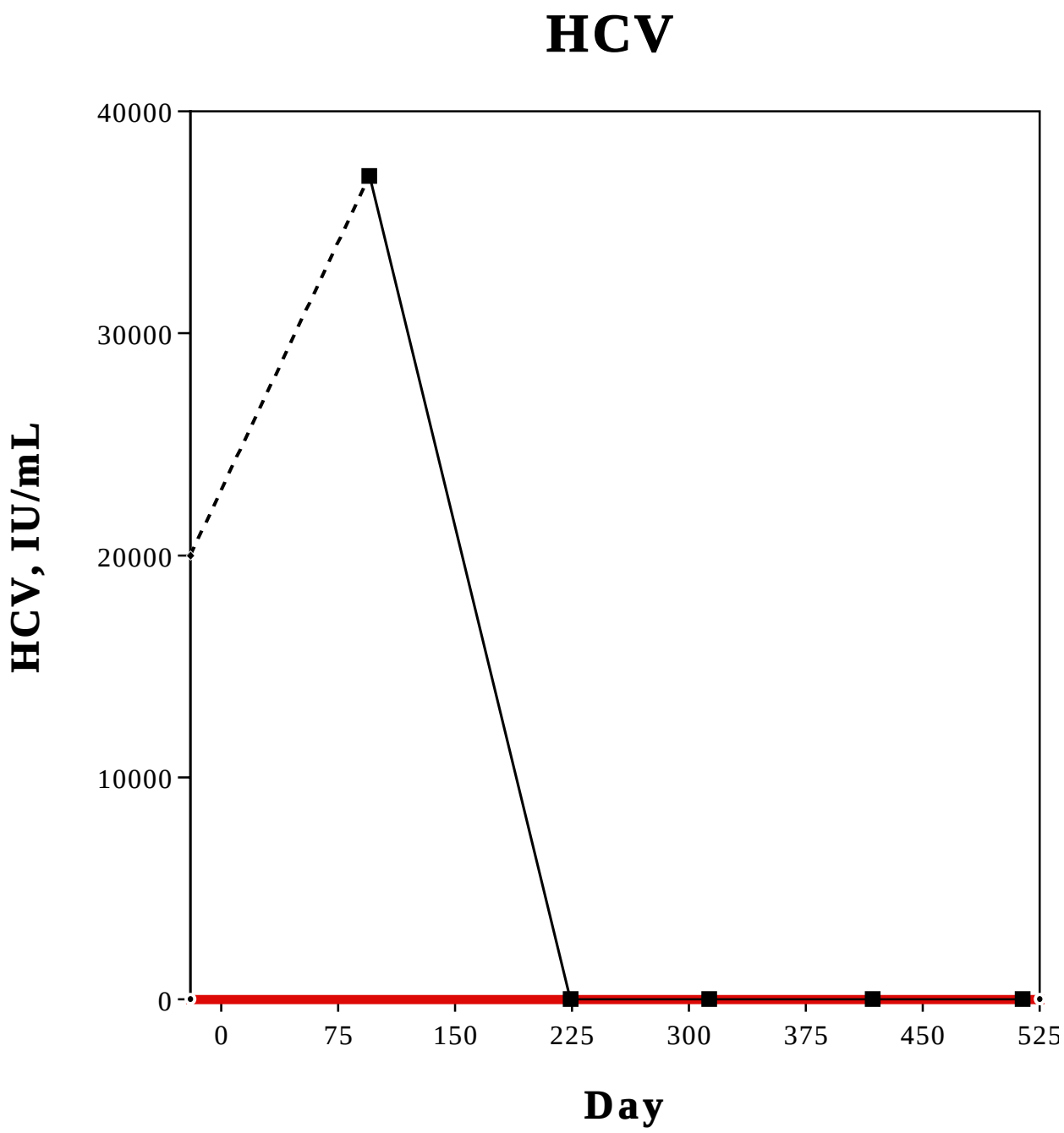

Hemoglobin
Hemoglobin, g/dL
18
17
16
15
14
13
12
11
10
0
75
150
225
300
375
450
525
Day


Hematocrit
Hematocrit, %
55
50
45
40
35
30
0
75
150
225
300
375
450
525
Day


RDW
RDW, %
18
16
14
12
10
0
75
150
225
300
375
450
525
Day


ALT
ALT, IU/L
125
100
75
50
25
0
0
75
150
225
300
375
450
525
Day


AST
AST, IU/L
60
50
40
30
20
10
0
0
75
150
225
300
375
450
525
Day


HCV
40000
30000
20000
10000
0
HCV, IU/mL
0
75
150
225
300
375
450
525
Day