Hepatitis B

General:

Hepatitis B virus (or Dane particle) is a particle with a diameter of 42 nm, consisting of a core and a coat, which contains partial double-stranded circular DNA and DNA polymerase; it belongs to the HEPADNA viruses. Incubation period is 60-180 days, the transmission is parenteral, sexual or perinatal. Prophylaxis: passive: immunoglobulin; prevention: vaccination (antibodies against surface Ag), infectiosity: highly infectious if HBe antigen is present.

Serological profile:

Stage	Hbs Ag	HBe Ag	aHBs	aHBc	aHBe	infectious	DNA
incubation period	+	+	-	-	-	+++	+/-
acute hepatitis B	+	+	-	+	-	+++	+
chronic active hepatitis B	+	+/-	-	+	-	+++	+
chronic active hepatitis B with a low virus activity	+	-	-	+	+/-	++	+/-
chron. persist. hepatitis B	+	-	-	+	+	+/-	+/-
carrier	+	-	-	-	-	+/-	+
early reconvalescence	+	+/-	+/-	+	+/-	++	+/-
late reconvalescence	+/-	-	+	+	+	-	+/-
healed hepatitis B	-	-	+	+	+	-	-
vaccination	-	-	+	-	-	-	-
see *	+		+				
see **	-	-	-	+	-	-	-

* simultaneously positive results for HBsAg and aHBs:

1. Reinfection with two subtypes of hepatitis B,

2.Elimination phase of HBs-Ag in the course of acute hepatitis B; observed after vaccination and in the Mediterranean area.

** isolated aHBc in:

1. connatal infected children,

2. chronic hepatitis B with low HBs-Ag concentration,

3. passive immunization

4. HBV infection with aHBs loss or in the “diagnostic window” of an acute infection, if HBs-Ag is no longer traceable .

The following tests are available:

- **Hepatitis B surface antigen, HBs-Ag**

General:

The presence of hepatitis B-surface antigen indicates acute or chronic hepatitis or carrier status.

Indication:	Suspicion of hepatopathy, infectivity status
Material:	2 ml serum
Stability:	14 days at 2 to 8°C
TAT:	same day, FML
Method:	ECLIA
Units:	COI
Ref.- range:	< 0.1
Note:	If the patient is taking multivitamins or dietary supplements containing high dose of Biotin (> 5 mg), the patient should stop taking it for at least 24 hours , before having the blood collection.

- **Hepatitis B surface antigen, confirmation test**

Material:	2 ml serum
Stability:	14 days at 2 to 8°C
TAT:	same day, FML
Method:	ECLIA (specific antibody neutralization)
Units:	qualitative

Ref.- range: negative

- **Hepatitis B surface antibody, HBs antibodies**

General:

The presence of HBs antibodies in serum indicates contact with hepatitis B virus (or HBV surface Ag in vaccination). Simultaneously detectable HBc antibodies indicate acquired immunity by HBV; HBsAbs without HBc antibodies indicate vaccination.

Indication:	Vaccinating status, immune status
Material:	1 ml serum
Stability:	6 days at 2 to 8°C
TAT:	same day, FML
Method:	ECLIA
Units:	IU/l
Ref.- range:	<10.0 (not immune)
	>15 (immune)
	>100 (optimal immunity)
Note:	If the patient is taking multivitamins or dietary supplements containing high dose of Biotin (> 5 mg), the patient should stop taking it for at least 24 hours , before having the blood collection.

- **Hepatitis B-core antibodies, HBc antibodies**

General:

The test detects core IgG and IgM antibodies combined in one test. HBc antibodies occur immediately after appearance of HBs-Ag.

Indication:	Suspicion of postacute hepatitis, immunity status
Material:	1 ml serum
Stability:	14 days at 2 to 8°C
TAT:	same day, FML
Method:	competitive ELISA

Units: COI
Ref.- range: >1.0
Note: If the patient is taking multivitamins or dietary supplements containing high dose of Biotin (> 5 mg), the patient should stop taking it for at least 24 hours , before having the blood collection.

- **Hepatitis B-core antibody, HBc antibodies, IgM**

General:

Patients with acute hepatitis B and with positive hepatitis B surface antigen (HBsAg) are usually anti-HBc IgM positive. The determination of anti-HBc IgM is also useful in detecting atypical hepatitis B virus infections without HBsAg in serum and, with some restrictions, in discriminating acute and chronic hepatitis type B. Chronic HBsAg carriers with severe liver disease have positive anti-HBc IgM more often than individuals with minor liver damage.

Material: 1 ml serum
TAT: 5-7 days*
Method: LIA
Ref.- range: see report
Note: If the patient is taking multivitamins or dietary supplements containing high dose of Biotin (> 5 mg), the patient should stop taking it for at least 24 hours , before having the blood collection.

- **Hepatitis B envelope antigen, HBe-Ag**

General:

The appearance of HBe-Ag points to the presence of infectious virus particles.

Indication: Assessment in hepatitis B infection
Material: 1 ml serum
Stability: 4 days at 2 to 8°C
TAT: same day, FML
Method: ECLIA
Units: COI
Ref.- range: <1.0
Note: If the patient is taking multivitamins or dietary supplements containing high dose of Biotin (> 5 mg), the patient should stop taking it for at least 24 hours , before having the blood collection.

- **Hepatitis B envelope antibodies, HBe antibodies**

General:

Anti-HBs and anti-Hbe antibodies can – together with anti-HBc antibodies – persist throughout life after infection and are characteristic for immunity. However, in most cases anti-Hbe antibodies show lower persistence and are below the detection limit after several years. Disappearance of Hbe antigen and the occurrence of anti-HBe indicate the transition into the nonreplicative phase.

Indication:	evaluation of infectivity, assessment of chronic hepatitis B
Material:	1 ml serum
Stability:	14 days at 2 to 8°C
TAT:	same day, FML
Method:	competitive ECLIA
Units:	COI
Ref.- range:	<1.0

- **Hepatitis B virus DNA, quantitative virus load**

Indication:	Assessment of hepatitis B infection, therapy monitoring
Material:	2.7 ml EDTA blood
Preanalytics:	for dispatch please do not freeze EDTA blood! Debris of erythrocytes will disturb the measurement. Alternative material is erythrocyte-free EDTA plasma, which can be dispatched frozen in an additive-free vial. Please use additional vials for other requested tests, as opening of the vial and splitting the samples can lead to contaminations and therefore to false positive results.
TAT:	7-10 days*
Method:	Cobas Ampliprep/ Taqman PCR
Units:	IU/ml
Ref.- range:	<10

- **Hepatitis B genotyping**

General:

Hepatitis B virus (HBV) has been classified into 8 genotypes (A-H) based on intergroup divergence of 8% or more in the complete nucleotide sequence. Furthermore, we know that there are many subtypes within some genotypes. In summary, HBV genotypes correlate with the clinical outcome of chronic HBV infection and response to treatment. The evidence is stronger between genotypes B and C and their response to interferon but not to nucleoside or nucleotide treatment. There is also a clear association between HBV genotypes and precore and core promoter mutations. Genotyping of HBV may remain a research tool unless we can prove that it can predict

the risk of adverse outcomes (fulminant disease, cirrhosis, HCC) or can influence therapeutic management.

Material: 2.7 ml EDTA blood
TAT: 7-10 days*
Preanalytics: for dispatch please do not freeze EDTA blood! Debris of erythrocytes will disturb the measurement. Alternative material is erythrocyte-free EDTA plasma, which can be dispatched frozen in an additive-free vial.
Method: PCR

- **Hepatitis B virus, PreCore mutations (Please note that this has been discontinued)**

General:

This test is indicated for patients with significant hepatitis B DNA replication in acute hepatitis (more than 105 copies/ml) but negative HBe Ag.

Material: 5 ml EDTA blood
TAT: 7-10 days*
Preanalytics: for dispatch please do not freeze EDTA blood! Debris of erythrocytes will disturb the measurement. Alternative material is erythrocyte-free EDTA plasma, which can be dispatched frozen in an additive-free vial.
Method: PCR and sequencing

- **Hepatitis B virus, Lamivudin resistance**

General:

Lamivudin is a nucleotide-analogon of HBV DNA. The DNA-polymerase of the HB virus cannot differentiate lamivudin from nucleotides and incorporates lamivudin, which in turn blocks the DNA-polymerase and thereby HBV replication.

Material: 5 ml EDTA blood
TAT: 7-10 days*
Preanalytics: for dispatch please do not freeze EDTA blood! Debris of erythrocytes will disturb the measurement. Alternative material is erythrocyte-free EDTA plasma, which can be dispatched frozen in an additive-free vial. Please use additional vials for other requested tests, as opening of the vial and splitting the samples can lead to contaminations and therefore to false positive results.
Method: PCR

For complete list of laboratory test offered at Freiburg Medical Laboratory, please visit http://www.fml-dubai.com/parameter-listings/