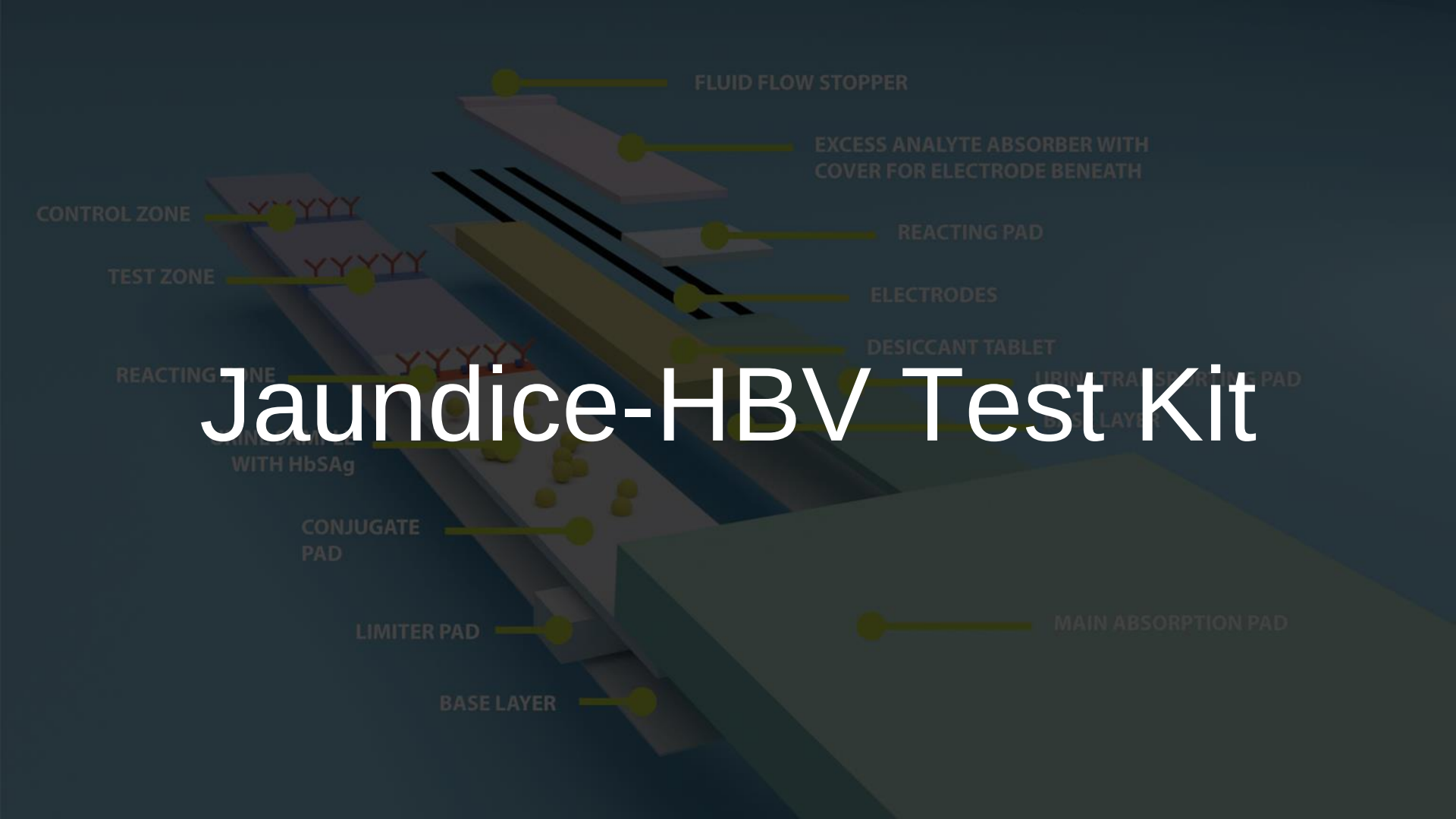
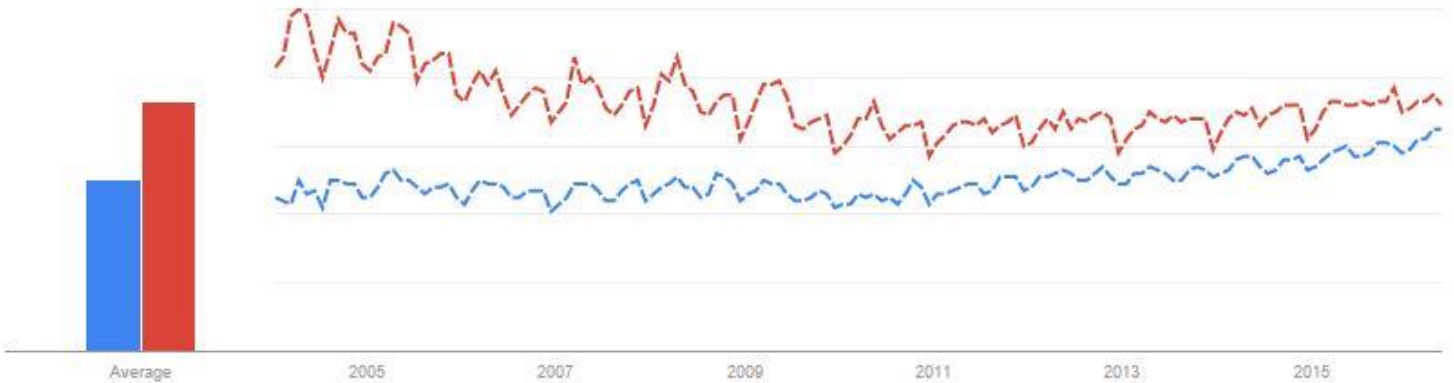


Jaundice-HBV Test Kit

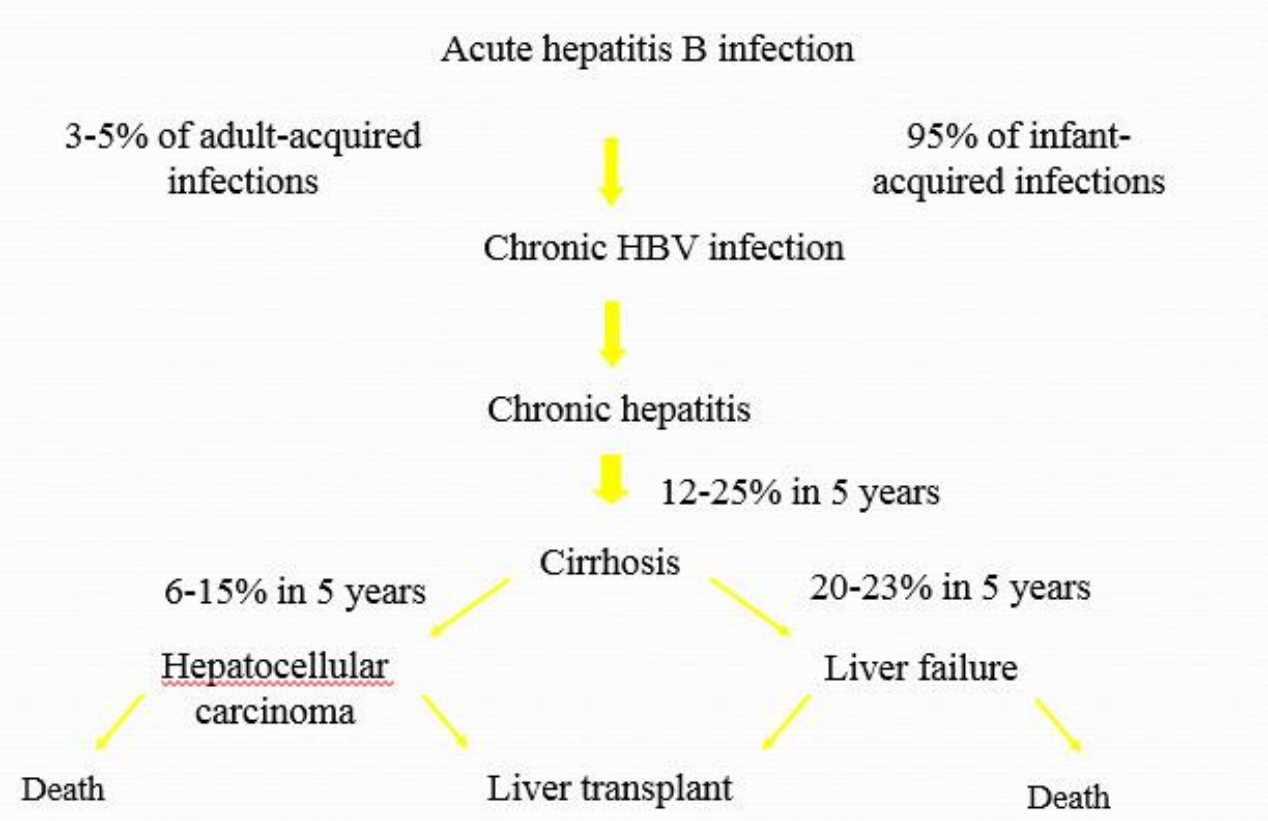
Survey


Hepatitis B
Jaundice
Region | City
Ghana 100
Angola 63
Uganda 49
Vietnam 43
Nigeria 35
Philippines 25
Kenya 22


Hepatitis B
Jaundice
Region | City
Nepal 100
Syria 76
Iran 72
Sudan 71
Kenya 68
Ghana 67
Nigeria 54


Average
2005
2007
2009
2011
2013
2015

Hepatitis B Virus and Causes



Jaundice and Causes

When the Test can be used?

1. When the eye turns yellow
2. When urine turns yellow and more concentrated.
3. When the individual is affected by Jaundice.
4. When the individual is suffering from malfunctioning of liver
5. When the individual got affected by any of the disease like Malaria, Sickle cell disease,Hereditary spherocytosis,Thalassemia,Glucose-6-phosphate dehydrogenase deficiency (G6PD)

Sample used in Test

The sample that going to be used in this Test kit is Urine.

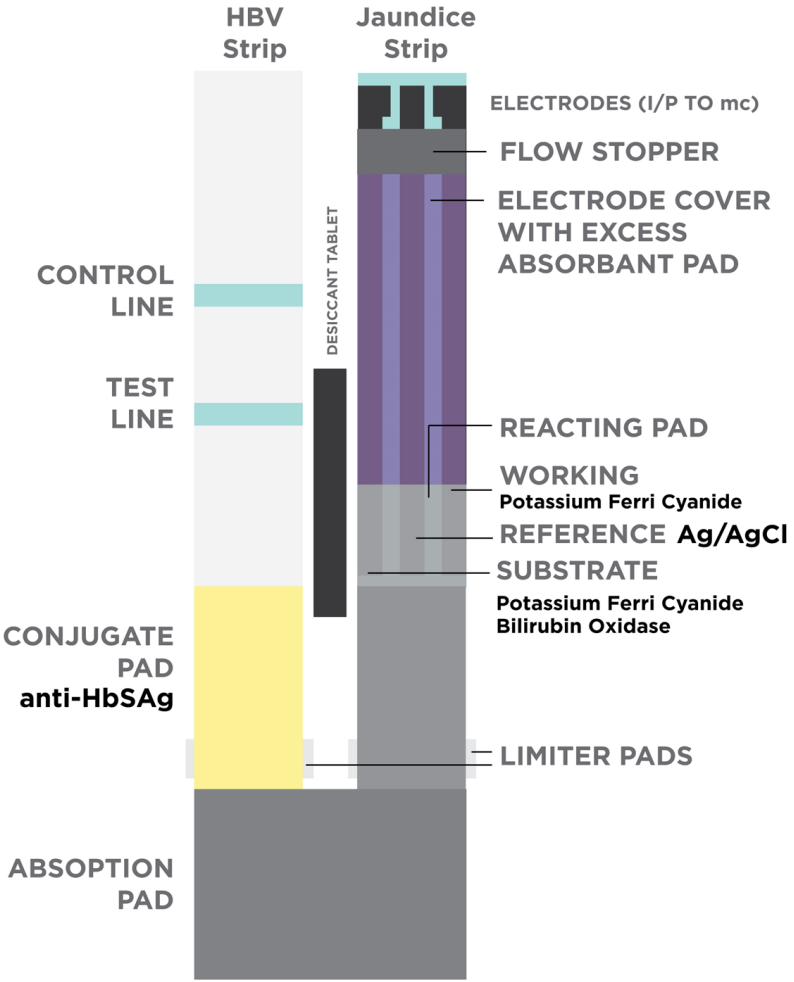
For detecting HbSAg and Bilirubin, Urine is used as an analyte for checking Jaundice and Hepatitis B.

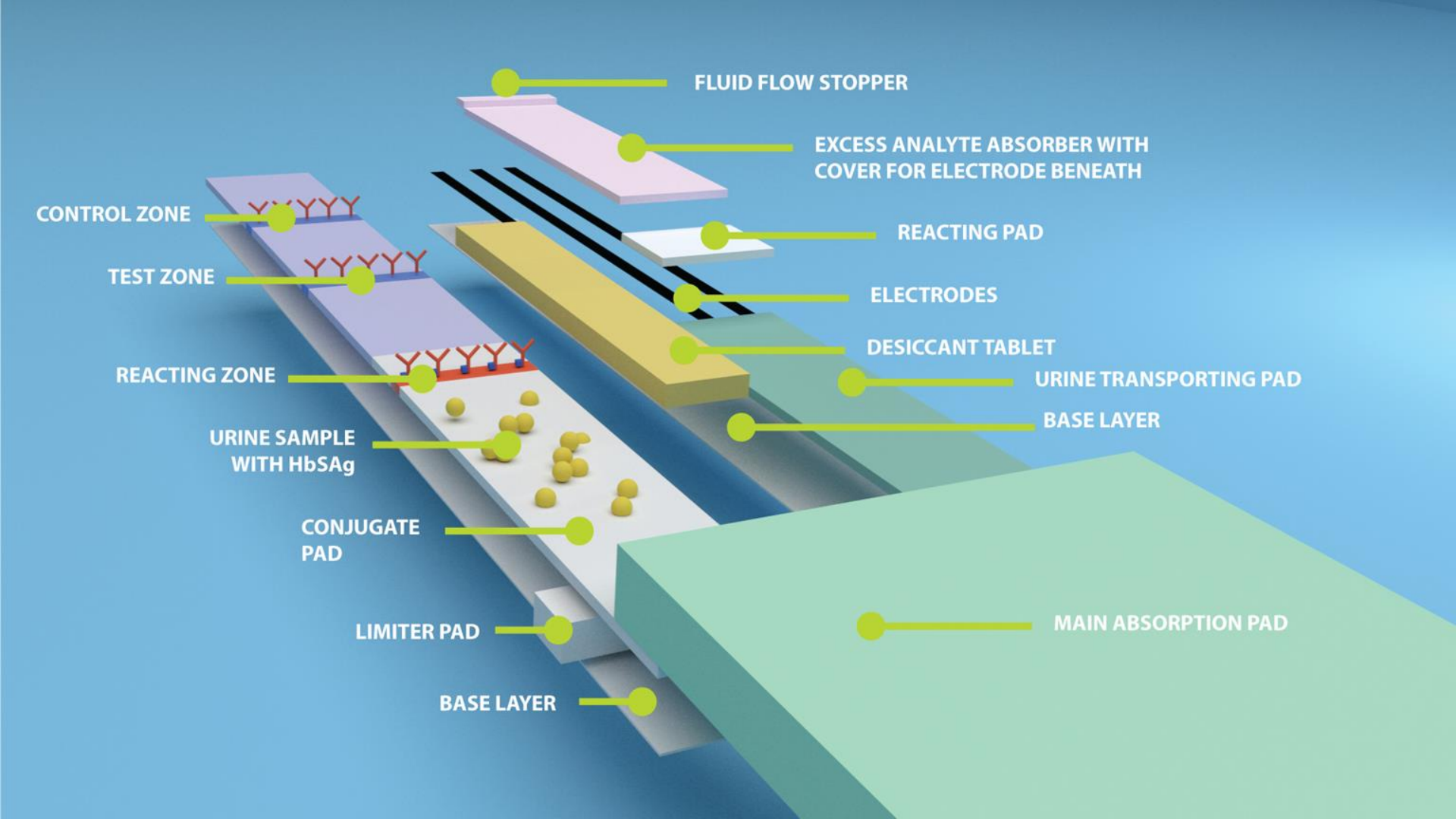
HbSAg	**Bilurubin**
Present or not	0 to 25 mg/dL.

Test Procedure

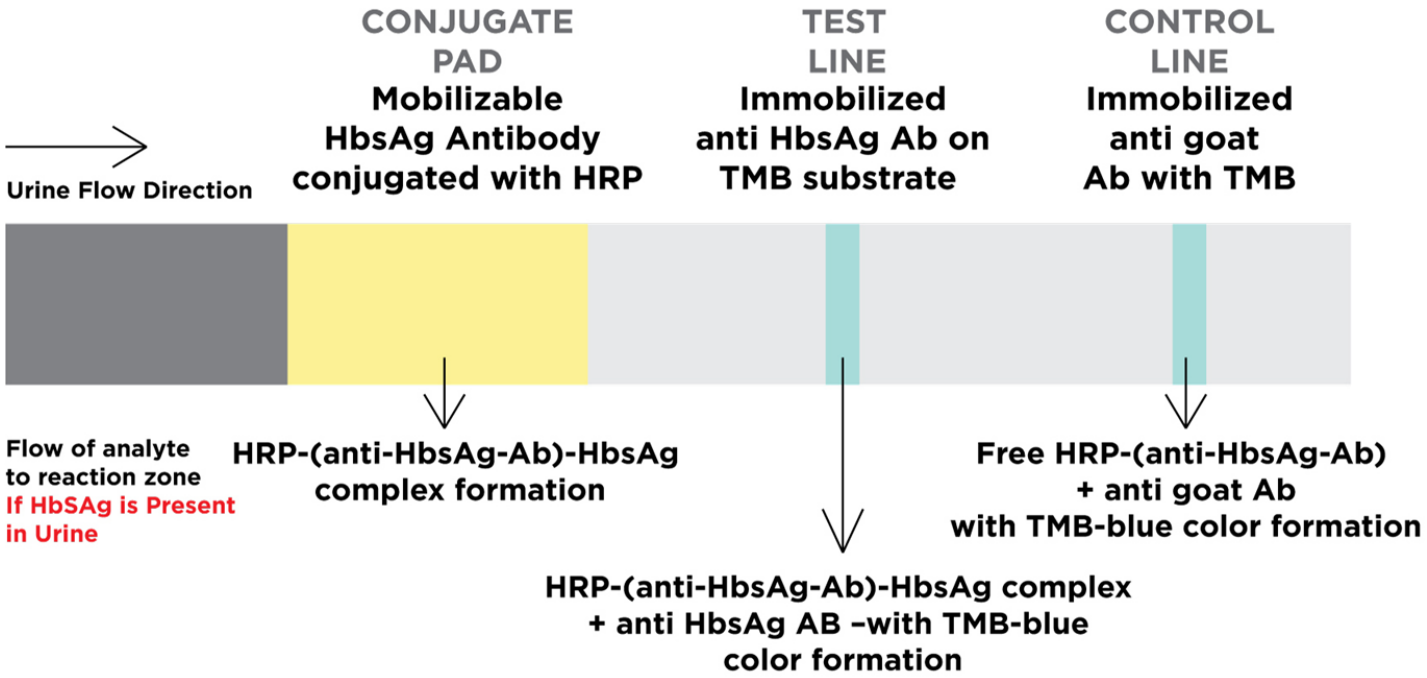
Block Diagram

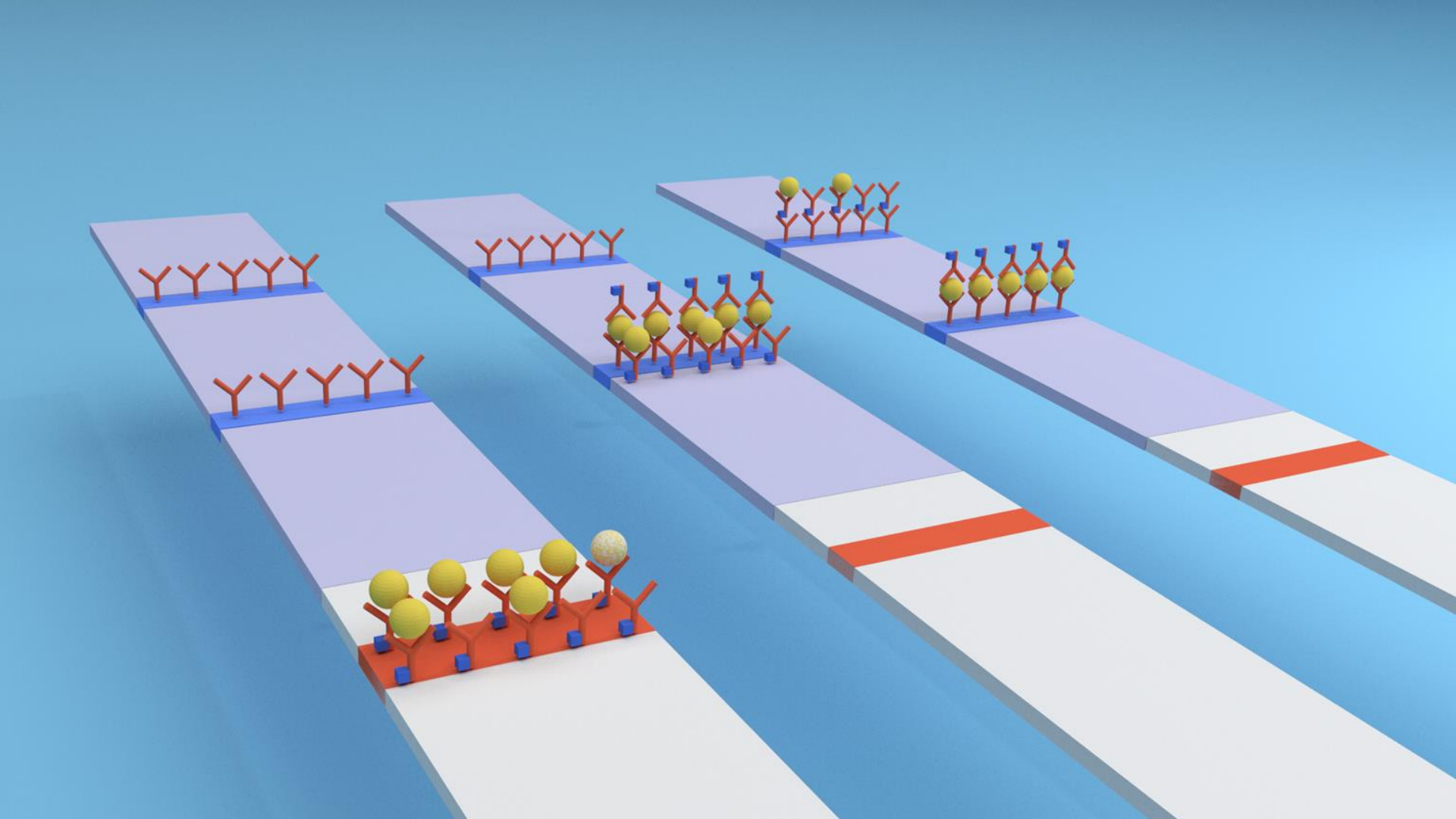
Section	HBV Strip	Jaundice Strip
Sample Handling	Absorption Pad	Absorption Pad
Capture Layer	Conjugate Pad	Reacting Pad
Transducer	Test Line-shows result in **optical form**	Electrodes-Current obtained through **electrochemical reaction**
Signal Detection	Color change detected by photodiode	Voltage change detected by potentiometers




FLUID FLOW STOPPER
EXCESS ANALYTE ABSORBER WITH COVER FOR ELECTRODE BENEATH
REACTING PAD
ELECTRODES
DESICCANT TABLET
URINE TRANSPORTING PAD
BASE LAYER
MAIN ABSORPTION PAD
CONTROL ZONE
TEST ZONE
REACTING ZONE
URINE SAMPLE WITH HbSAg
CONJUGATE PAD
LIMITER PAD
BASE LAYER

HBV Strip

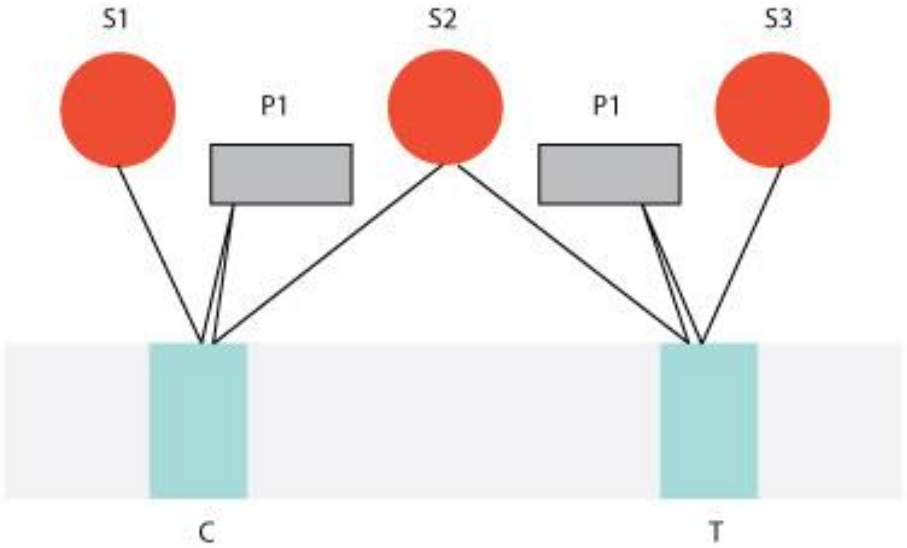

CONJUGATE PAD
Mobilizable HbsAg Antibody conjugated with HRP
TEST LINE
Immobilized anti HbsAg Ab on TMB substrate
CONTROL LINE
Immobilized anti goat Ab with TMB
Urine Flow Direction
Flow of analyte to reaction zone
If HbSAg is Present in Urine
HRP-(anti-HbsAg-Ab)-HbsAg complex formation
HRP-(anti-HbsAg-Ab)-HbsAg complex + anti HbsAg AB –with TMB-blue color formation
Free HRP-(anti-HbsAg-Ab) + anti goat Ab with TMB-blue color formation



Signal Detection and processor

HBV Strip: Using Optical method

The device housing comprises an analytical assembly labelled (**10**), which comprises as circuit board (**12**) supporting two LEDs and two photodiodes (**14**), aligned with a test zone of a nitrocellulose strip lateral flow strip (16) which is in liquid flow communication with the sampling portion (4) of the liquid transport or carrier. The test zone is the zone in which a labelled reagent accumulates in the presence (or absence, as appropriate) of the analyte of interest. This accumulation affects the optical property of the test strip (**16**), such as its reflectivity or transmissivity, a property that can be measured by the LED/photodiode arrangement. The arrangement produces an output current, the magnitude of which is related to the amount of label accumulated in the test zone.

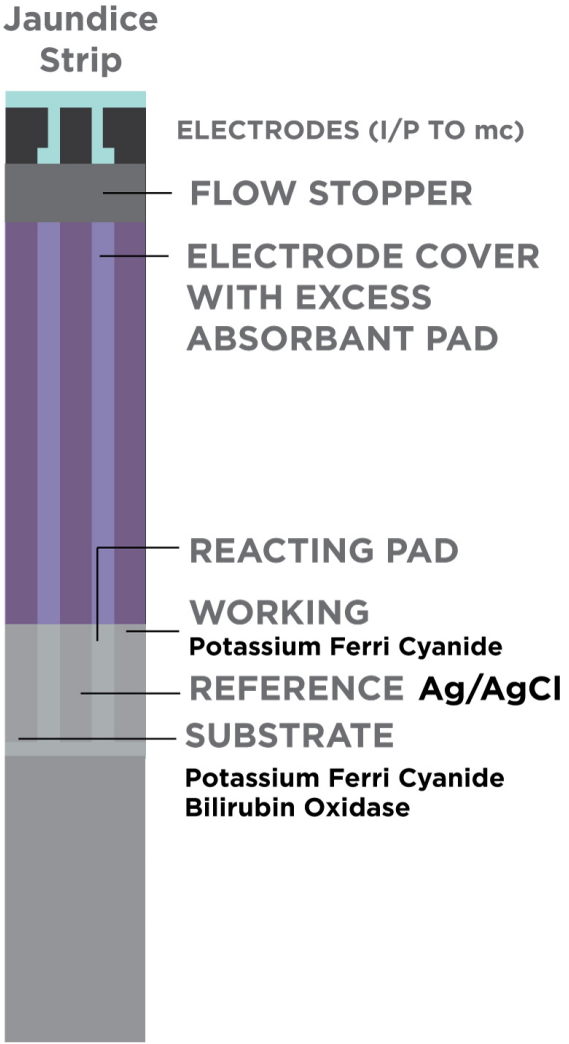


Jaundice Strip

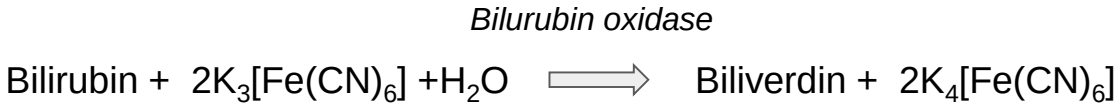
Working electrode - loaded with oxidizing reagent potassium ferri cyanide

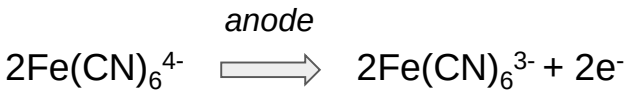
substrate electrode - loaded with same oxidizing reagent along with chemical reagent(bilirubin oxidase) that consumes bilirubin before being oxidized by the mediator

Reference elctrode may be loaded with Ag/Agcl.



Signal Detection



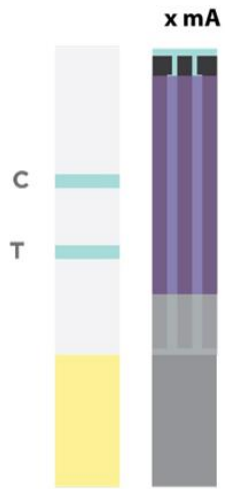


Signal Detection and processor

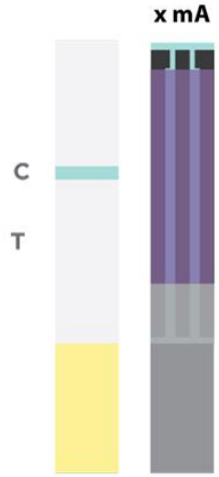
Hepatitis B Bilurubin - 13.5 mg/dl	No Hepatitis B Bilurubin - 13.5 mg/dl	No Hepatitis B No Bilurubin
Both Bilurubin and HbSAg are present	Bilurubin is present but no HbSAg	No Bilurubin or HbSAg

Display

Photodiode voltage and electrode voltage as input to Microprocessor

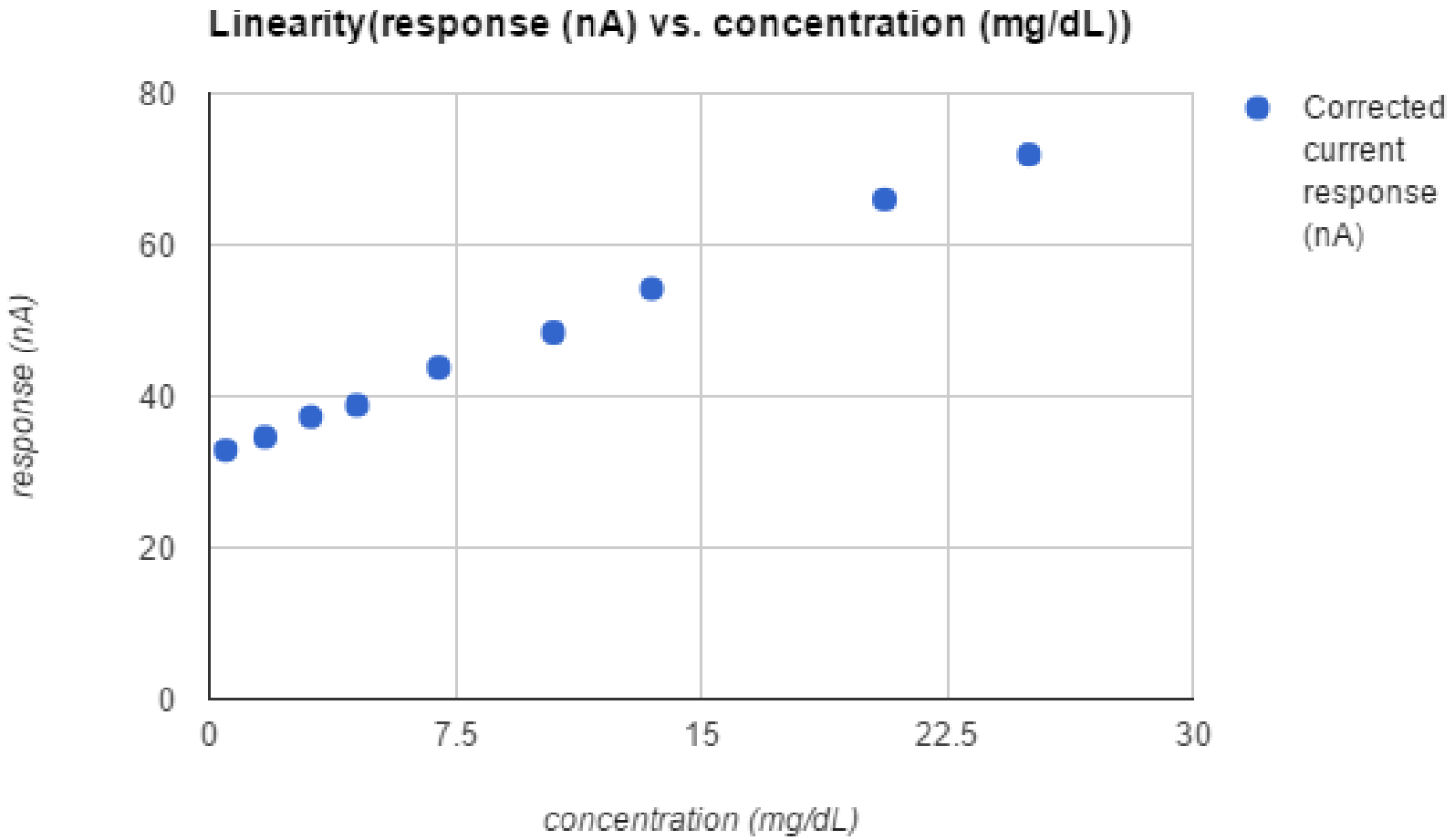


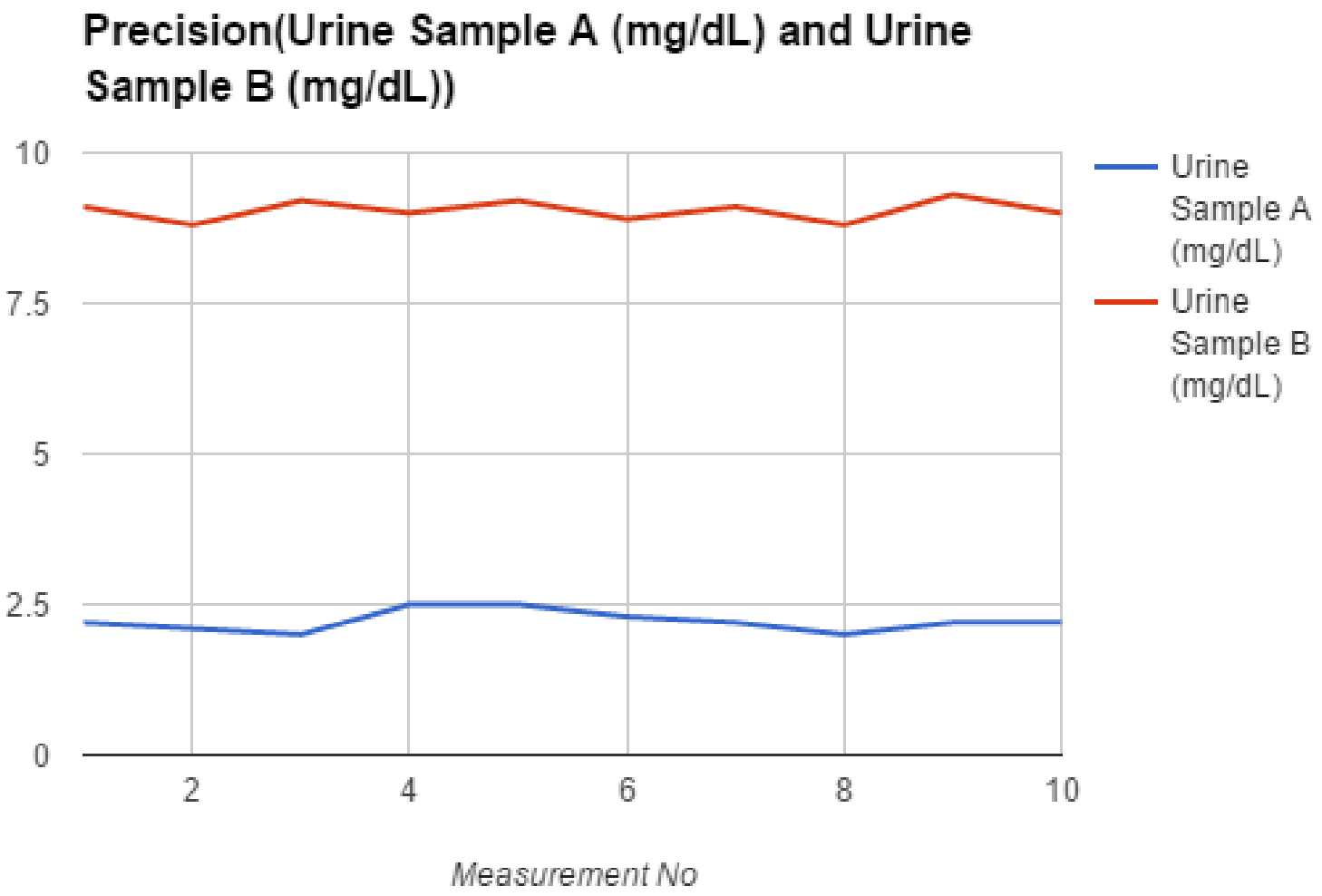
Case 1

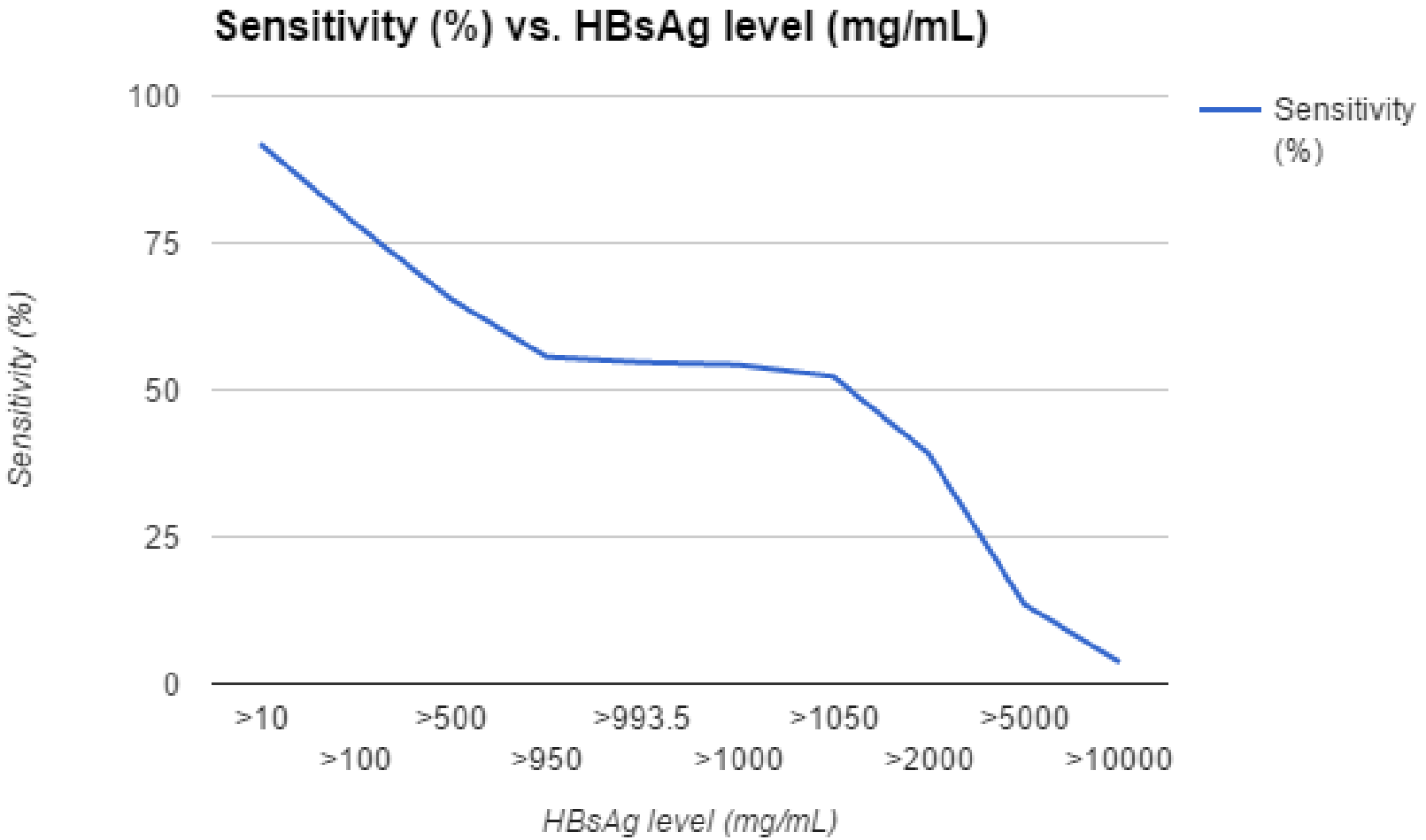


Case 2

Case 3


Linearity(response (nA) vs. concentration (mg/dL))
80
60
40
20
0
response (nA)
0
7.5
15
22.5
30
concentration (mg/dL)
Corrected current response (nA)


Precision(Urine Sample A (mg/dL) and Urine Sample B (mg/dL))
10
7.5
5
2.5
0
2
4
6
8
10
Measurement No
Urine Sample A (mg/dL)
Urine Sample B (mg/dL)


Sensitivity (%) vs. HBsAg level (mg/mL)
100
75
50
25
0
Sensitivity (%)
Sensitivity (%)
>10
>100
>500
>950
>993.5
>1000
>1050
>2000
>5000
>10000
HBsAg level (mg/mL)

Signal Detection and processor

Positive results (quantitative hepatitis B surface antibody [anti-HBs] levels of > or =**12.0 mIU/mL**) indicate adequate immunity to hepatitis B from past hepatitis B or HBV vaccination. After receiving a primary HBV vaccine series, individuals with anti-HBs levels of 12 mIU/mL or greater are considered protected from hepatitis B in accordance with the CDC guideline.(1)

A negative result (quantitative anti-HBs level of <**5.0 mIU/mL**) indicates a lack of recovery from acute or chronic hepatitis B or inadequate immune response to HBV vaccination. The U.S. Advisory Committee on Immunization Practices does not recommend more than 2 HBV vaccine series in nonresponders.(1)

Indeterminate results (quantitative anti-HBs levels in the range from > **or =5 to <12 mIU/mL**) indicate inability to determine if anti-HBs is present at levels consistent with recovery or immunity. Repeat testing is recommended in 1 to 3 months.

Reference

1. Jaundice in Adults-http://www.medicinenet.com/jaundice_in_adults/page3.htm
2. Hepatitis B- http://www.who.int/mediacentre/factsheets/fs204/en/
3. Designs, formats and applications of lateral flow assay: A literature review - http://www.sciencedirect.com/science/article/pii/S131961031400129X
4. Multiple analyte assay device with sample integrity monitoring system- https://www.google.com/patents/US6514769
5. An integrated electrochemical device based on immunochromatographic test strip and enzyme labels for sensitive detection of disease-related biomarkers-Zhe-Xiang Zoua,b, Jun Wangb, Hua Wangb, Yao-Qun Li a,*, Yuehe Linb,**
6. Electrochemical reaction of Bilurubin-http://www.google.com/patents/US7749766
7. Electrochemical sensing in paper-based microfluidic devices-https://gmwgroup.harvard.edu/pubs/pdf/1077.pdf
8. DesiccantTablets-http://packagingmaterial.jamesdawson.com/item/diagnostic-medical-industries-desiccant/desiccant-tablets/dt

Reference

10. US 20140273028 A1-http://www.google.com/patents/US20140273028

11. Hepatitis B Surface Antibody, Qualitative/Quantitative, Serum-http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8254

System and method for reading a test strip-https://www.google.com/patents/EP1952121A2

Devices, methods, and test kits for electronic analyte assaying -https://www.google.com/patents/US20130217136

11. All Graphics designed in Adobe Illustrator, Blender 3D, Excel Charts, Google Analytics.