

Briefing Note for the Editorial Advisory Group April 2021

Proposed remodeling of Positive and Negative findings in the 118245000 |Measurement finding (finding)| hierarchy

Purpose:

- To seek agreement from members of the EAG on the remodeling of measurement findings that currently state a “positive” or negative” result for a particular laboratory test.
- If the members agree to the changes proposed to then discuss and agree on a migration pathway for existing content.

Background:

The QI project is currently addressing the hierarchy 118245000 |Measurement finding (finding)|.

Many, but not all of the measurement findings relate to an interpretation of results that are presented along a continuous, quantitative scale (e.g. blood glucose, bilirubin, or white blood cell count). The findings are then represented as being either above, below, or within a given laboratory reference range. The reference range is defined for a specified “normal” population and derived by taking the average plus or minus 2 standard deviations from the average. Where a patient’s results fall outside the reference range the clinician must make a judgment based upon this result within the context of other laboratory and clinical findings before coming to a clinical diagnosis.

In addition to the reference range findings, this hierarchy includes a number of concepts (128) that interpret the findings of the laboratory test as either “Negative” or Positive”. These statements are potentially problematic as they may be interpreted as stating that a particular disorder is excluded or confirmed.

Mis-interpretation of these finding statements may arise due to an incomplete understanding of the limitations of the test used:

- a test with high sensitivity giving rise to false positives.
- a test with high specificity giving rise to false negatives.

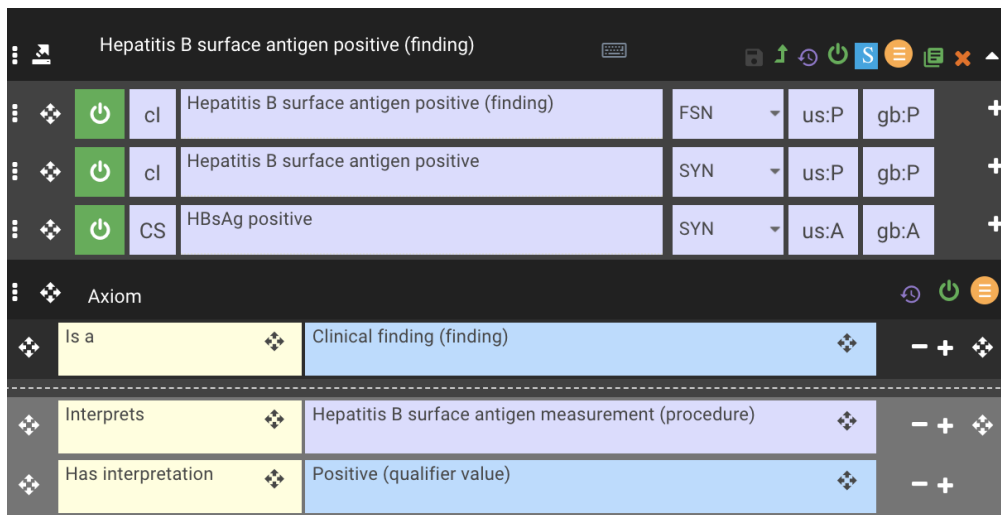
- recognizing that a “negative” result is based on the limit of detection of the test and not on the true presence or absence of the substance being tested for.
- the natural tendency to assume a positive test implies more than is appropriate for a given laboratory test.

Proposal:

In light of the issues raised above, and to provide a clear unambiguous statement of the meaning of these concepts it is proposed that the concepts currently expressed in terms of either a “positive” or “negative” finding should be restated as being “detected” or “not detected”. For example:

165806002 | Hepatitis B surface antigen positive (finding) |

Current modeling:

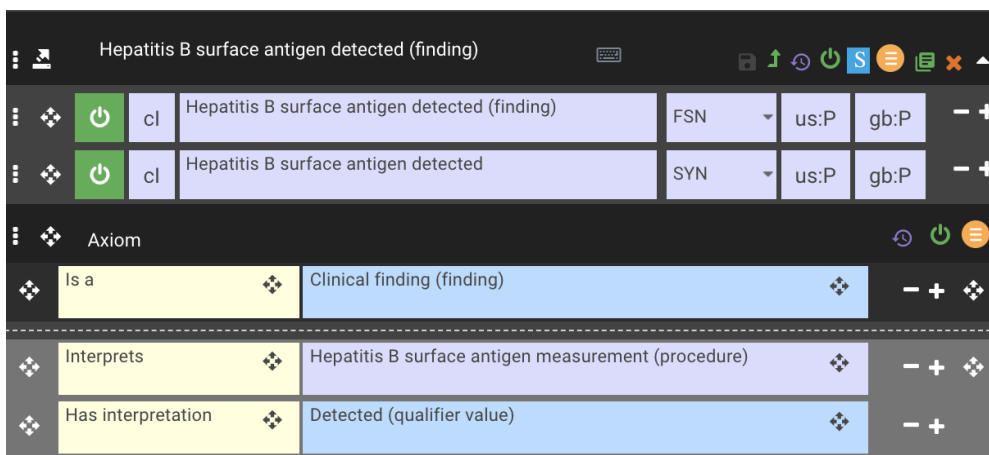


Hepatitis B surface antigen positive (finding)					
cl	Hepatitis B surface antigen positive (finding)	FSN	us:P	gb:P	
cl	Hepatitis B surface antigen positive	SYN	us:P	gb:P	
CS	HBsAg positive	SYN	us:A	gb:A	
Axiom					
Is a	Clinical finding (finding)				
Interprets	Hepatitis B surface antigen measurement (procedure)				
Has interpretation	Positive (qualifier value)				

Would be restated as:

Hepatitis B surface antigen detected (finding)

Updated modeling:

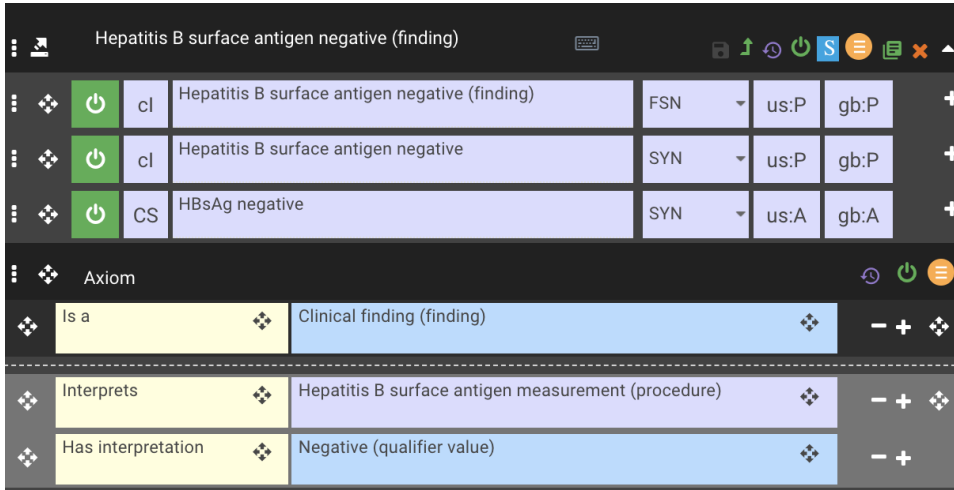


Hepatitis B surface antigen detected (finding)					
cl	Hepatitis B surface antigen detected (finding)	FSN	us:P	gb:P	
cl	Hepatitis B surface antigen detected	SYN	us:P	gb:P	
Axiom					
Is a	Clinical finding (finding)				
Interprets	Hepatitis B surface antigen measurement (procedure)				
Has interpretation	Detected (qualifier value)				

...and

406010001 | Hepatitis B surface antigen negative (finding) |

Current modeling:

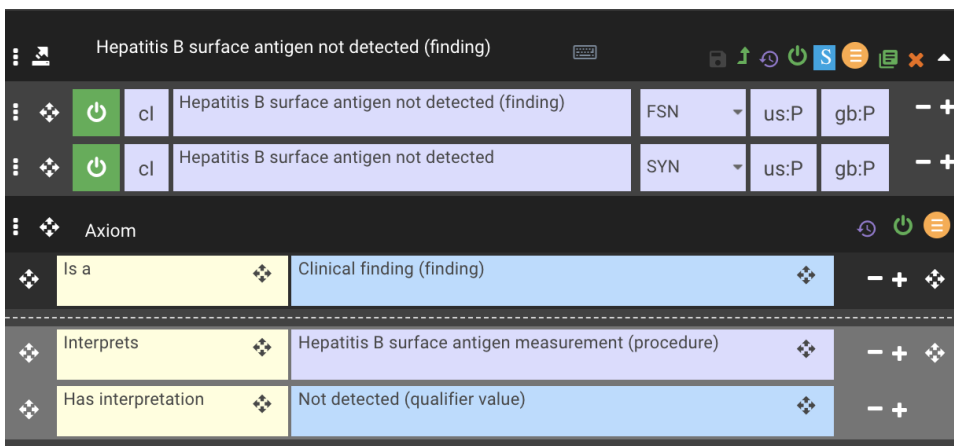


Hepatitis B surface antigen negative (finding)						
cl	Hepatitis B surface antigen negative (finding)	FSN	us:P	gb:P		+
cl	Hepatitis B surface antigen negative	SYN	us:P	gb:P		+
CS	HBsAg negative	SYN	us:A	gb:A		+
Axiom						
Is a	Clinical finding (finding)					- +
Interprets	Hepatitis B surface antigen measurement (procedure)					- +
Has interpretation	Negative (qualifier value)					- +

Would be restated as:

Hepatitis B surface antigen not detected (finding)

Updated modeling:



Hepatitis B surface antigen not detected (finding)						
cl	Hepatitis B surface antigen not detected (finding)	FSN	us:P	gb:P		- +
cl	Hepatitis B surface antigen not detected	SYN	us:P	gb:P		- +
Axiom						
Is a	Clinical finding (finding)					- +
Interprets	Hepatitis B surface antigen measurement (procedure)					- +
Has interpretation	Not detected (qualifier value)					- +

Please note: The observables project has sanctioned the use of 260373001 |Detected (qualifier value)| and 260415000 |Not detected (qualifier value)| for detecting the presence of organisms

Migration of existing content:

In order to agree on a suitable migration pathway, we must first establish whether changing the FSN from “xxxx positive” to “xxxx detected” and “xxx negative” to “xxx not detected” fundamentally changes the meaning of the concept or makes explicit that which was always implicit due to the limitations of the laboratory testing method used.

Therefore, the options are:

1. Inactivate existing content as “Erroneous” (because we are saying that the existing FSN does not represent the limitations of the laboratory test) and replace it with the proposed concepts as indicated in the proposal above.
2. Inactivate the existing FSN/PT and replace it with the wording as indicated above.
3. Include a synonym of “xxx positive” or “xxx negative” as appropriate and inactivate the existing FSN/PT and replace it with the wording as indicated above.

Whichever option is chosen will require consultation with the community of practice given the importance of laboratory findings in clinical records.