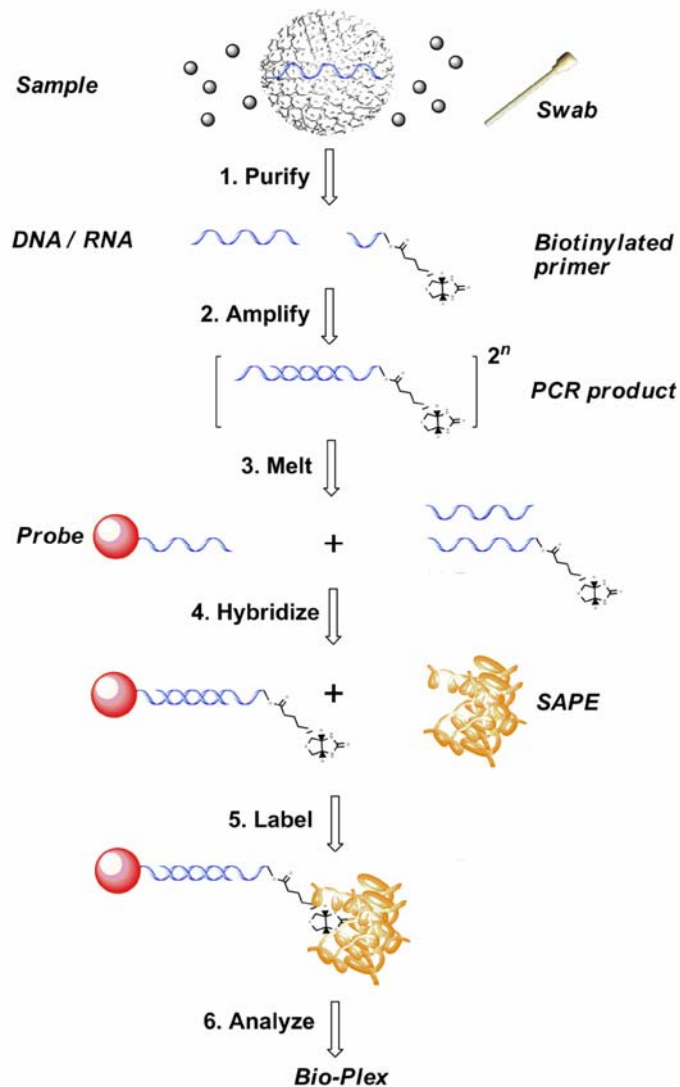


## Jim Case Attachment A

### Introduction:

New technologies utilizing organism-specific unique sequences of either nucleic acid or proteins have recently been developed that allow for the rapid identification of the presence of these “signatures” in a variety of sample matrices. These technologies utilize combinations of polymerase chain reaction, fluorescence activated cell sorting and flow cytometry to determine the presence or absence of an agent in sample material. Utilizing Luminex technology (<http://www.luminexcorp.com/technology/index.html>), upwards of 100 analytes may be measured in a single reaction vessel. A schematic of the process is shown below.



**Problem:**

During a pilot project to test the ability to communicate results from this assay using HL7 version 2.6 messages with LOINC and SNOMED as the terminologies for the OBX segment, it was brought to light that each signature would require a separate LOINC code. While on the surface this does not appear to be a problem until one realizes that for the pilot program, we had as many as 4 different signatures for a single organism (in this case, a virus). The signatures went through rigorous analysis to ensure their uniqueness from all organisms, leading to the high specificity for the assay. However, each signature was only given a local identifier. Because of the lack of a registry for signature sequences as well as the proprietary nature of some of these “designer” sequences” there is currently no guaranteed way to communicate the signature used in a particular assay.

For example, if we have 3 signatures for Foot and Mouth Disease, they have been named FMDV-1, FMDV-2 and FMDV-3. There is nothing to prevent another research laboratory to develop other signature sequences for FMDV called FMDV-1, FMDV-2 and FMDV-3 that do not in any way correspond to the sequences of the original lab.

**Question:**

Given the facts that 1) there will most likely not be a registry of signature sequences that can assign unique IDs the various agents and 2) this technology will be increasingly important in the growing efforts for rapid diagnostics in the animal and human public health arena and 3) both research labs and diagnostic laboratories wish to distinguish the individual results for each signature,

What are recommended ways to represent these observation names in LOINC or using LOINC and other attributes in the OBX segment (version 2.x) or Observation Class (version3) in HL7 messages?