



Next Level™ FISH with Cell Enrichment

Next Level™ FISH with Cell Enrichment is positioned for the detection and monitoring of patients at risk for bladder cancer.

PLUS Diagnostics utilizes an exclusive industry leading technology; Cell Enrichment, resulting in an increased target cell population resulting in a better assay and leading to a more definitive diagnosis.

Next Level™ FISH with Cell Enrichment is an in-house validated modification to the FDA approved UroVysion® kit. The difference in Next Level™ FISH with Cell Enrichment relative to the UroVysion® protocol relates specifically to the section in the kit insert titled "Specimen Processing and Preparation".

PLUS uses a cell enrichment method prior to the sample processing steps outlined in the UroVysion® insert. Post enrichment all steps of sample processing are as outlined in the insert. The enrichment process is performed on the whole urine. A cocktail of magnetic beads is poured into the urine sample. These beads are coated with a variety of cell specific antibodies which distinguish other cell types from the target population of Urothelial cells. A magnetic field is then introduced to segregate those cells to which the beads have bound to surface receptors from those cells which have no bound beads. The result produced is a urothelial cell enriched sample. PLUS's Next Level™ FISH with Cell Enrichment results in an average increase in target cell populations of greater than 20% generating a better assay, leading to a more definitive diagnosis.

The second process affected is in slide preparation. The Abbott slide prep protocol is labor intensive and wastes valuable sample through trial and error in concentrations. We utilize the ThinPrep 2000 assay manufactured by Cytoc for the slide preparation process. Cytoc has a program specific to making slides for UroVysion® testing named UroCyte and is considered industry standard. It was developed to address the limitation of the Slide Preparation process as outlined in the UroVysion® kit insert and creates efficiencies. This method of slide making is widely employed by many reference labs and is marketed for this purpose by Cytoc. As a result of these two enhancements PLUS has validated that less probe is required.

As a result of these two enhancements PLUS has validated that less probe is required. A validation was performed to evaluate the enrichment process. The final validation determined what amount of probe is required and proved that the amount of probe can be reduced with no adverse effects on the test outcome.

The performance characteristics of our Next Level™ FISH with Cell Enrichment has been validated internally by PLUS Diagnostics and is provided in accordance with CLIA and CAP guidelines and regulations. PLUS has performed this protocol for all external proficiency tests and has never failed a proficiency exam using this process. It has been in place for almost two years and we have processed over 30,000 cases in this fashion.