STRAND DIAGNOSTICS
know error®

5770 Decatur Boulevard
Indianapolis, IN 46241
888-924-6779
www.knowerror.com

Contact:
Linda Tuttle
ltuttle@knowerror.com

FOR IMMEDIATE RELEASE

Strand Diagnostics protects over 200,000 patients from biopsy specimen contaminations

Indianapolis, Indiana (December 1, 2015) -- Through the use of Strand Diagnostics' patented **know error® system** over 200,000 biopsy patients have been protected from occult specimen contaminations and switching errors that happen during the surgical biopsy process; keeping them safe from a cancer misdiagnosis and adverse cancer therapy.

The diagnostic testing cycle for cancer can involve up to 18 steps and several medical professionals working in different locations and the possibility of specimen provenance contamination is a serious concern for both physicians and patients.

The **know error® system** utilizes bar coding, forensic principals and DNA Specimen Provenance Assay (DSPA) testing to compare the DNA profile of the patient's cheek swab (reference) to the DNA profile of the tissue used in the cancer diagnosis. An exact match of these profiles confirms the cancer tissue is free of admixture (specimens containing another's DNA) and belongs exclusively to the ascribed patient giving him or her and the ordering physician the peace of mind to move forward with a personalized treatment plan.

As the therapy for a cancer patients becomes more personalized with biomarker testing it is important to understand the rate at which specimen provenance contaminations occur.

Dr. John D. Pfeifer along with several colleagues published a study[1] in the October 2015 American Journal for Clinical Pathology (AJCP) determining the amount of human-to-human specimen contamination that is present in cancer tissues used for biomarker testing.

In evaluating the extent of contamination in clinical next-generation sequencing (NGS) data the findings suggest that 2% of NGS samples tested were so significantly contaminated by another's DNA that test results were confounded. The data also suggest an inverse correlation between the amount of DNA used for NGS studies and the likelihood of significant contamination.

The study estimated the percent admixture based on frequencies of the read haplotypes at loci that showed evidence for contamination. Of the 296 consecutive cases, nine (3%) had at least 5% DNA admixture. Eleven more cases were considered not-contaminated in this study but had evidence of low-level allocontamination of less than 5%. In concluding the researchers suggest utilizing tools for detecting human-to-human specimen contamination in clinical NGS testing especially as laboratories trend toward using smaller amounts of input DNA.

Incorporating Stand Diagnostics' **know error® system** with DNA Specimen Provenance Assay (DSPA) testing

-more-

5770 Decatur Boulevard
Indianapolis, IN 46241
888-924-6779
www.knowerror.com

-more-

into the routine procedure for surgical biopsy evaluation detects occult specimen contamination before misattributing the biomarker test results in error.

For more information about DNA Specimen Provenance Assay (DSPA) and the **know error® system** visit www.knowerror.com.

About Strand Diagnostics
Strand Diagnostics is a molecular diagnostic testing company using cutting edge technology focused on advanced forensic services and is certified to perform medical testing nationally by CLIA, Clinical Laboratories Improvements Amendments. Our healthcare division developed and markets the **know error® system** used by physicians and laboratories to confirm cancer patients are always matched with their appropriate diagnosis. The patented **know error® system** with DNA Specimen Provenance Assay (DSPA) protects the integrity of clinical data by detecting instances of specimen handling errors before initiating treatment.

1. Jennifer K. Sehn, MD, David H. Spencer, MD, PhD, John D. Pfeifer, MD, PhD, Andrew J. Bredemeyer, PhD, Catherine E. Cottrell, PhD, Haley J. Abel, PhD and Eric J. Duncavage, MD. Occult Specimen Contamination in Routine Clinical Next-Generation Sequencing Testing. American Journal of Clinical Pathology. October 2015;144:667-674.

####