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**Presentation for CLIA General Comment Session
Potential for Waiver of Automated Hematology Devices**

Good afternoon and thank you for allowing me to address you today.

My name is Paul Rust and I am the Vice President of Point of Care Testing for Quest Diagnostics and the President of HemoCue, Inc., a Quest Diagnostics company. My 40 year career in the laboratory industry includes management of moderate and high complexity reference labs and the development of central lab hematology differential counters and physician office analyzers.

My goal today is to introduce you to the notion of having a simple, single analyte White Blood Cell analyzer approved for CLIA Waiver status. The device, manufactured by HemoCue, was developed to provide users with an accurate White Blood Cell count.

Several years ago HemoCue approached the FDA with an idea to create a White Blood Cell Analyzer that would be simple to use and as accurate and reliable as the HemoCue hemoglobin devices in wide use under CLIA waiver status. The company believed that since Hemoglobin and spun hematocrits were simple enough to be performed as CLIA waived tests, it should be possible to develop a device for WBCs. Throughout the development process the theme was to develop a product that met the CLIA Waiver Draft Guidelines, in effect at the time. In essence, this is a product developed for the typical CLIA Waiver user. The system uses approximately 30 error codes and alerts to identify out of range high and low specimens, and virtually all of the issues that a qualified medical technologist might encounter in the pre-analytic, analytic and post-analytic process. In short, modern software technology can replace the user expertise required to do a WBC under a microscope or in a multi-parameter device in a Moderately Complex lab.

For 25 years HemoCue has supplied extremely reliable and accurate devices to measure hemoglobin. When the company started, there were many skeptics who believed the manual copper sulfate method was good enough. Now there are hundreds of thousands of hemoglobin devices in use in physician offices, hospitals, rural clinics, blood bank donation centers, community health centers and throughout the world in remote locations, where the battery powered devices are the only lab instruments that can function where there is no electricity. Try telling a user in sub-Saharan Africa that these devices are too complicated to use while they are paddling their canoe to a remote village to test children for anemia. They appreciate the lifetime calibration and accuracy, robustness and reliability of the other single analyte device for hemoglobin quantification.

It is not the intention of the company to replace centralized laboratory testing with a simple WBC and, or Hemoglobin determination. The concept is to provide choice to the physician at the point of care for some patients, some of the time. Pediatricians may have keen interest in knowing if a white count is markedly elevated for patients that present with symptoms of *otitis media*, as just one example. The system is designed to augment centralized testing when it makes sense for the physician to have accurate information available while the patient is present. We believe physicians will determine if a patient needs a thorough hematology testing protocol performed by a centralized lab when leukemia may be suspected and will quickly adopt appropriate uses for a simple and accurate White Blood Cell count if such a system is widely available.

We ask that you consider this technology as a logical follow-on development of the HemoCue Hemoglobin device, known the world over as the little red box.

Thank you very much.

Paul Rust