Lack of standardized, reproducible protocols and reference values are among the challenges faced when using new or upgraded versions of instruments in Andrology and ART laboratories. This includes C6A or flow cytometers and other instruments. Any change in the setting of the standard instrument, including upgrades of hardware or software can lead to different results and may affect clinicians’ decision for treatment.

The goals of this study were:

- Compare the concordance correlation, sensitivity and specificity of the SDF results from standard (C6 Standard) and newer version (C6 Plus) of the same instrument with unadjusted setting and after adjustment with the standard settings.
- Establish the analytical validity of a new model of flow cytometer utilizing the current flow cytometer as the Standard.
- Compare the inter- and intra-observer variability on both flow cytometers.
- Establish the agreement between two observers’ precision and accuracy of the newer model of the flow cytometer.
- Validate C6 and C6 Plus instrumentation and use for clinical laboratory.

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