

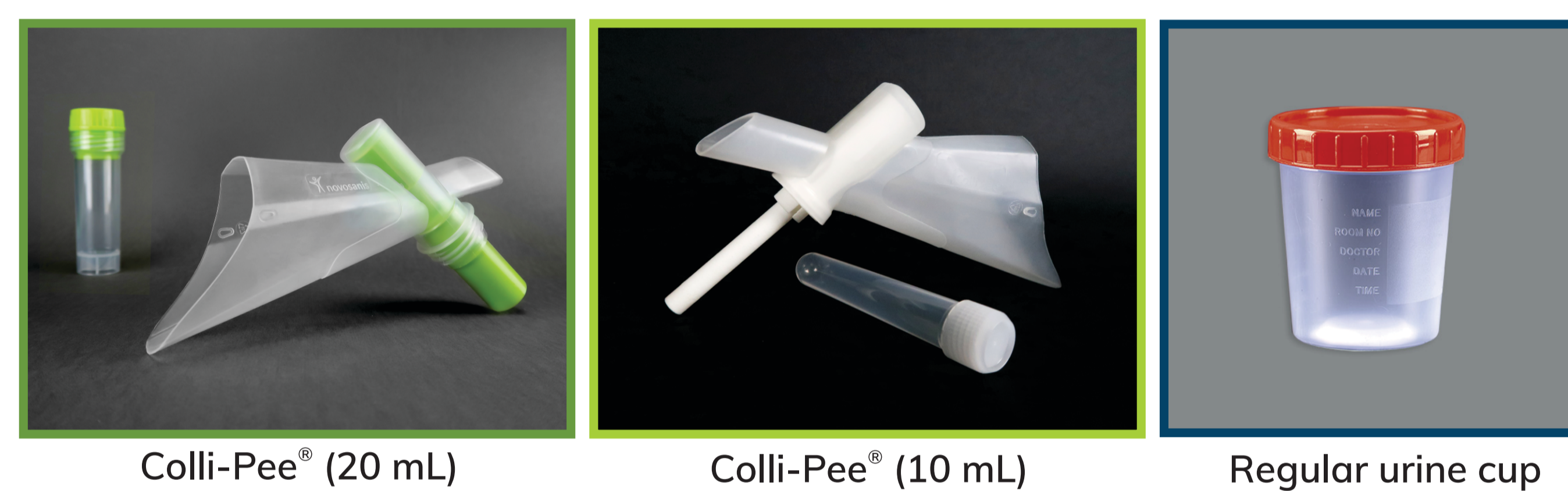
## BACKGROUND

A properly collected first-void (FV) urine sample is vital for accurate detection of sexually transmitted infections (STIs) and Human Papillomavirus (HPV). FV urine contains more DNA as well as other analytes improving diagnostic sensitivity of STIs.

FV urine collection is often still done with a standard urine cup. After the initial flow, patients are asked to interrupt the flow and direct the remaining urine in the toilet. This process is uncomfortable and error-prone. In recent years, collection devices such as Colli-Pee® are developed to facilitate and standardize the volumetric collection of FV urine.

The aim of this study was to:

- (1) evaluate the accuracy in volume of FV urine collected using Colli-Pee®, a first-void urine capturing device,
- (2) compare the collected volume with a standard urine cup.



## METHODS

A total of 563 participants were included in three studies. Each donor was asked to collect a FV urine sample, not having urinated 1 to 2 hours prior to collection, using one of the Colli-Pee® device variants (20 mL or 10 mL).

The participants were also asked to collect a second FV urine sample of 20 mL using a standard urine cup. A total of 443 samples were obtained.

The volume of the sample collected was calculated by:

- (1) subtracting the total weight of the collected sample plus collection device by the weight of an empty collection device or
- (2) pipetting the sample volume from the tube.

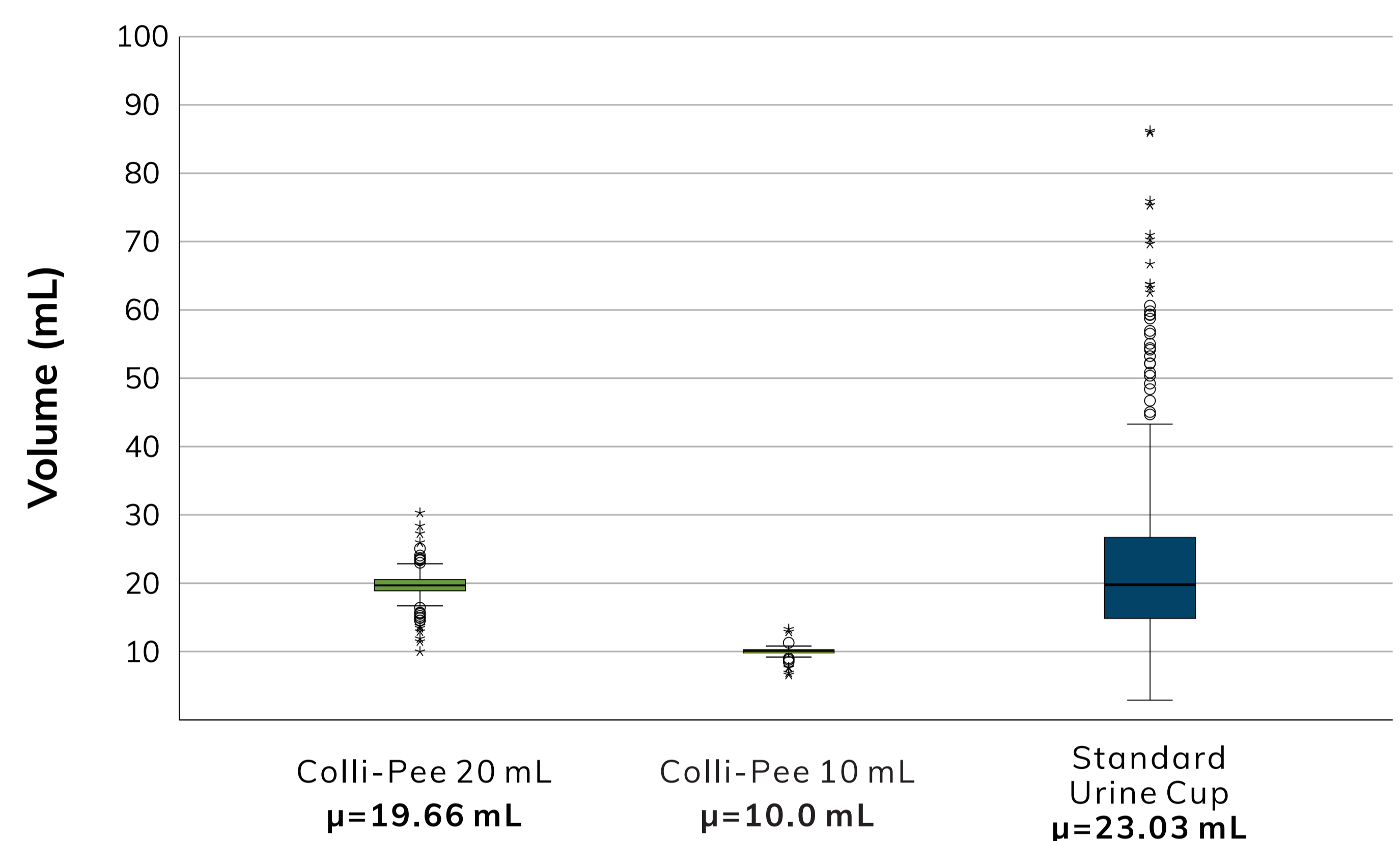


## RESULTS

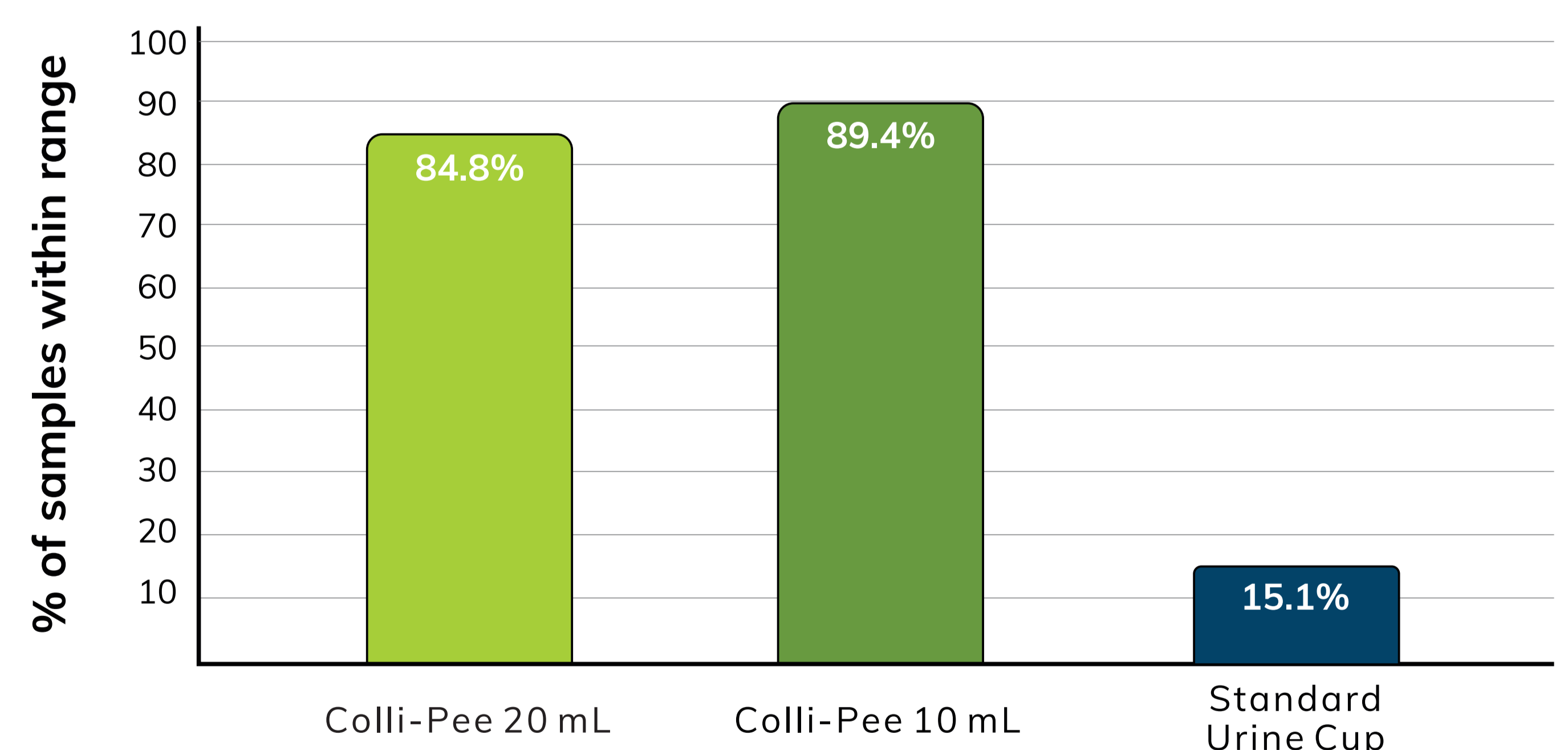
Four participants likely did not complete the collection using the Colli-Pee® device since the collected volume was lower than the initial buffer solution. These participants were seen as outliers and excluded from analysis, giving a total of 559 samples collected with Colli-Pee®.

The volume of sample collected with Colli-Pee® was consistently around the targeted volume of the collector tube: (a) 20 mL variant – Average volume collected: 19.66 mL (SD=1.83 mL) and (b) 10 mL variant – Average volume collected: 10.0 mL (SD=0.89 mL).

The volume collected with a standard urine cup varied significantly from the targeted 20 mL volume: Average volume collected: 23.03 mL (SD=13.48 mL).



For further analysis, by setting the acceptance range of the captured volume to 18-22 mL and 9-11 mL, the results show a significant difference (Pearson Chi-Square,  $p < 0.005$ ) between the collection methods. For Colli-Pee® 20 mL and 10 mL respectively, 84.8% and 89.4% of the collected samples are within this specified range, while only 15.1% of the samples collected with a standard urine cup fall in this 18-22 mL range. There is also a significant difference (Fisher's Exact Test,  $p < 0.005$ ) for samples that fall out of this specified range, with 82.3% coming from samples collected using a standard urine cup, while only 17.7% from those collected using the Colli-Pee®.



## CONCLUSION

The Colli-Pee® device allows for more accurate and volumetric collection of first-void urine (20 mL or 10 mL) compared to a standard urine cup, highlighting the importance of a collection device for sample collection. This way Colli-Pee® enables reliable urinary HPV and STI testing.