

Clinical Experience with a DNA Specimen Provenance Assay

- **DSPA test:** DNA matching of biopsy specimen to patient reference sample (buccal swab) to detect SPCs
- **Specimen Provenance Complications (SPCs)**
 - Type 1: Specimen transposition
 - Type 2: Specimen contamination
- **Reviewed: Specimens tested 10/1/16- 9/30/18**

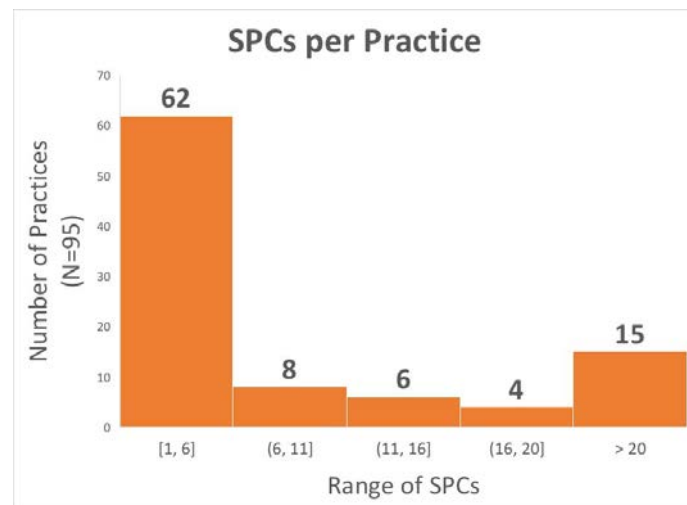


Patients Swabbed	104,894
Patients Tested	52,610 (50.1%)
Specimens Tested	136,594 (2.6 cores/patient)
Labs Providing Specimens	95

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- 1,059 SPC events total (2% cases):
 - Type 1: 89 (0.17%)
 - Type 2: 970 (1.84%)

Time Period	Type 1 SPCs (%)	Type 2 SPCs (%)	Total SPCs (%)
Period 1	28 (0.24%)	203 (1.75%)	237 (1.99%)
Period 2	25 (0.20%)	240 (1.91%)	268 (2.10%)
Period 3	22 (0.17%)	235 (1.77%)	258 (1.94%)
Period 4	14 (0.09%)	292 (1.93%)	307 (2.02%)
Total	89 (0.17%)	970 (1.84%)	1,059 (2.01%)



- Conclusions:
 - SPCs occur in 2% of prostate biopsies
 - All practices experience SPCs
 - DSPA testing is critical to ensure accurate biomarker results and appropriate patient management