

Detection of CIN2+ in women with Normal Cytology using a 3-type HPV mRNA test

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No conflicts of interests to declare



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Background

- Despite organized screening in Norway, the incidence of CxCa in young women is increasing
- Twenty five percent of all women diagnosed with CxCa had normal cytology within 3 years of cancer diagnosis
- Risk of CxCa is 2-3 pr 10,000 women with normal cytology
- HPV type 16, 18 and 45 cause 90% of CxCa in women < 40 years

Munoz N et al (2004) *Int J Cancer* **111**(2):278-285

www.kreftregisteret.no/arsrapport-livmorhalsprogrammet-2015

www-dep.iarc.fr/NORDCAN/english/StatsFact.aspxcancer=212&country=578

Objectives

- To estimate the detection rate of CIN2+ in women with normal cytology by rescreening “normal” PAP smears from HPV mRNA 16, 18, and 45 positive samples
- To evaluate if an HPV mRNA test (PreTect SEE) can improve screening program sensitivity without an excessive follow up workload

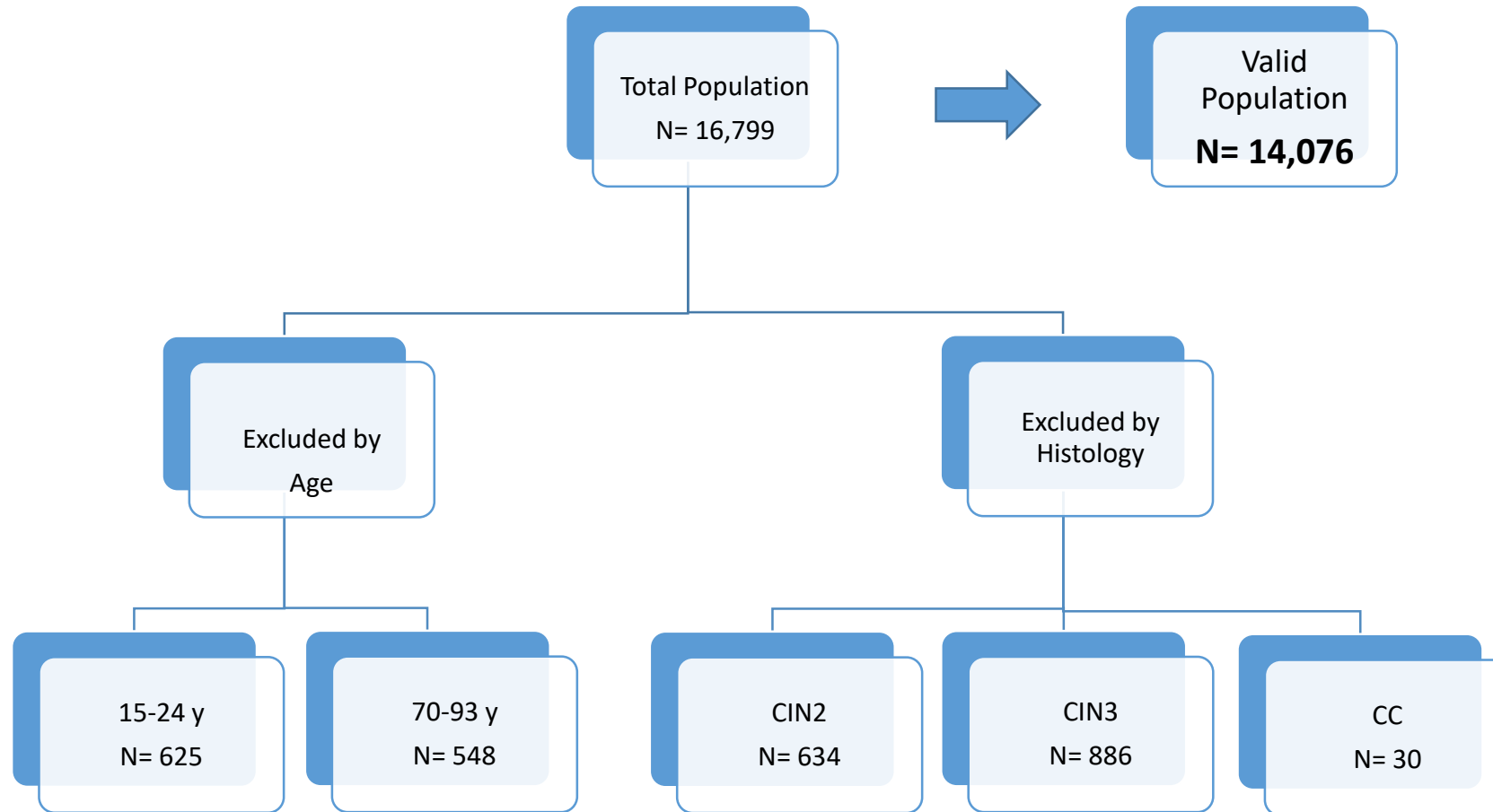
Methods

The study was initiated by Clinical Pathology, University Hospital of North Norway starting in April 2016 (cont.)

- Women diagnosed with normal PAP smears were tested with PreTect SEE (individual genotyping of E6/E7 mRNA HPV 16, 18 and 45)
- PAP smears with positive PreTect SEE were rescreened
- Women with revised cytology diagnosis were followed up according to national guidelines

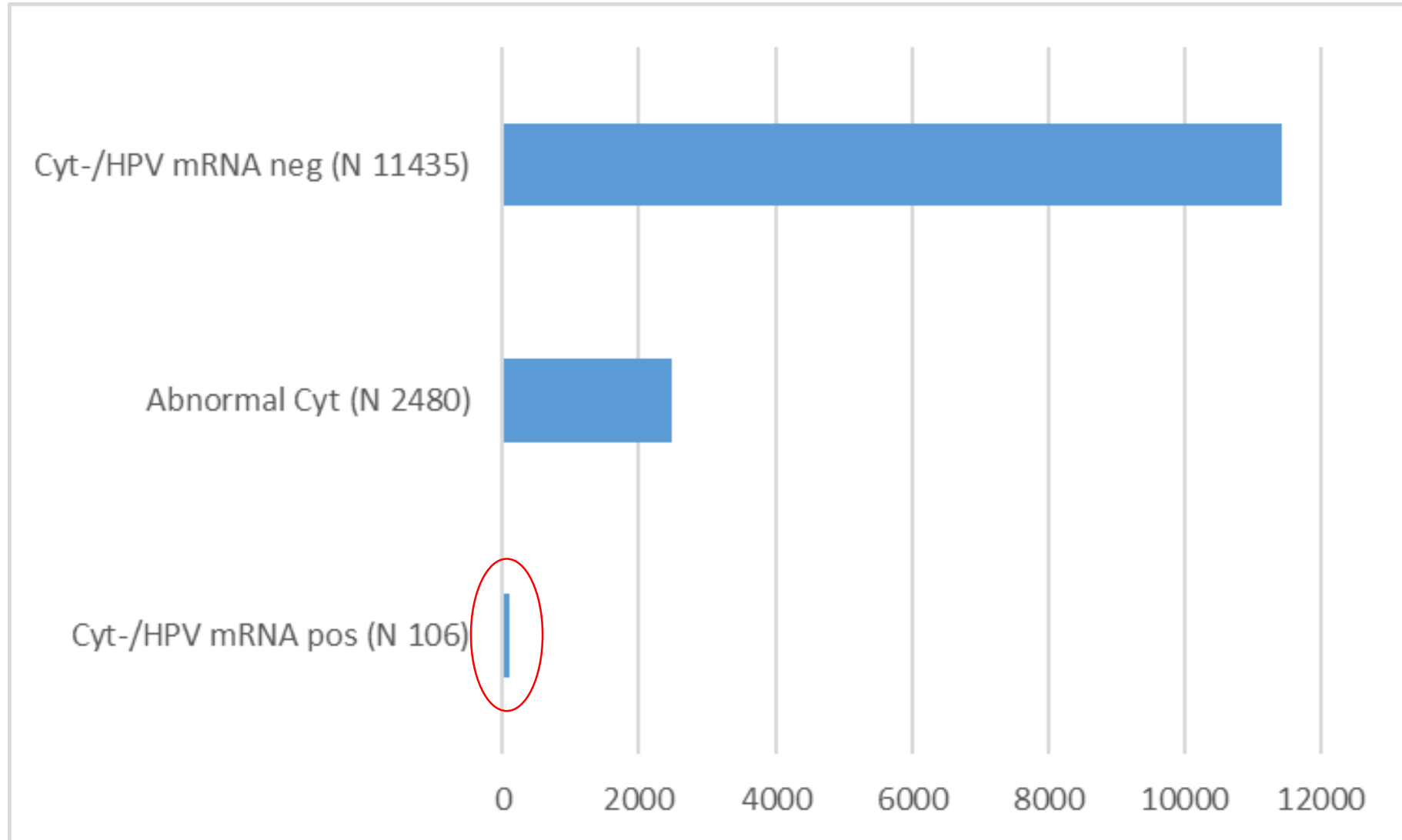
Study Population

Women in Troms and Finnmark County (2016)



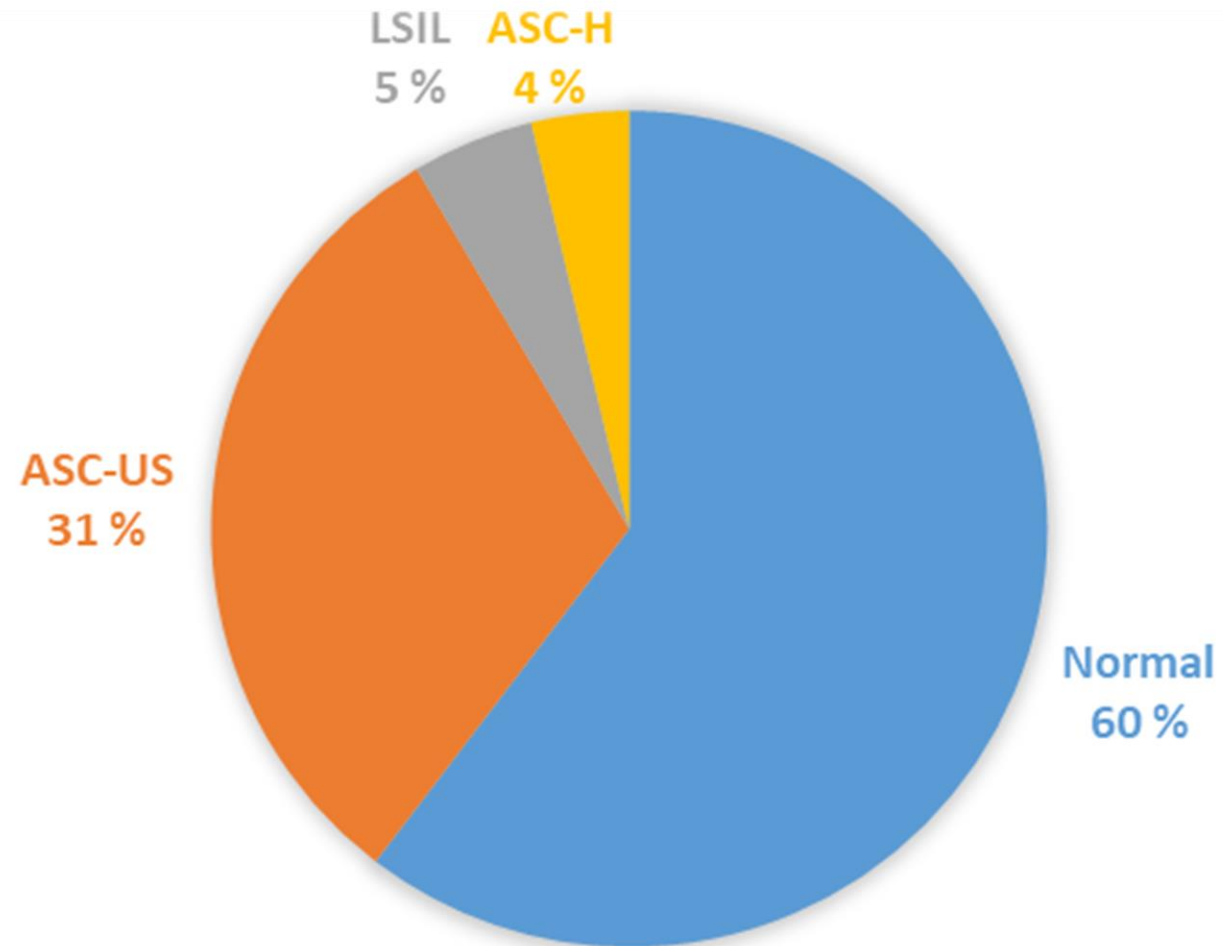
Index Cytology

Positivity Rate PreTect SEE: **0.9%** (106/11,541)



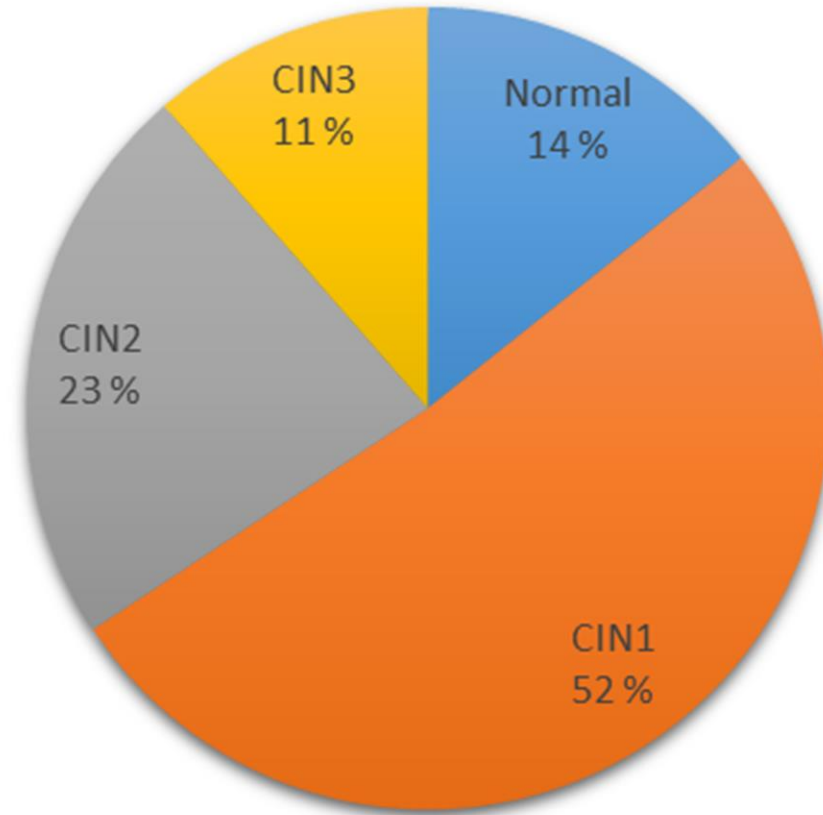
Rescreening of Index Cytology

Revised Diagnosis: **39.6%** (42/106)



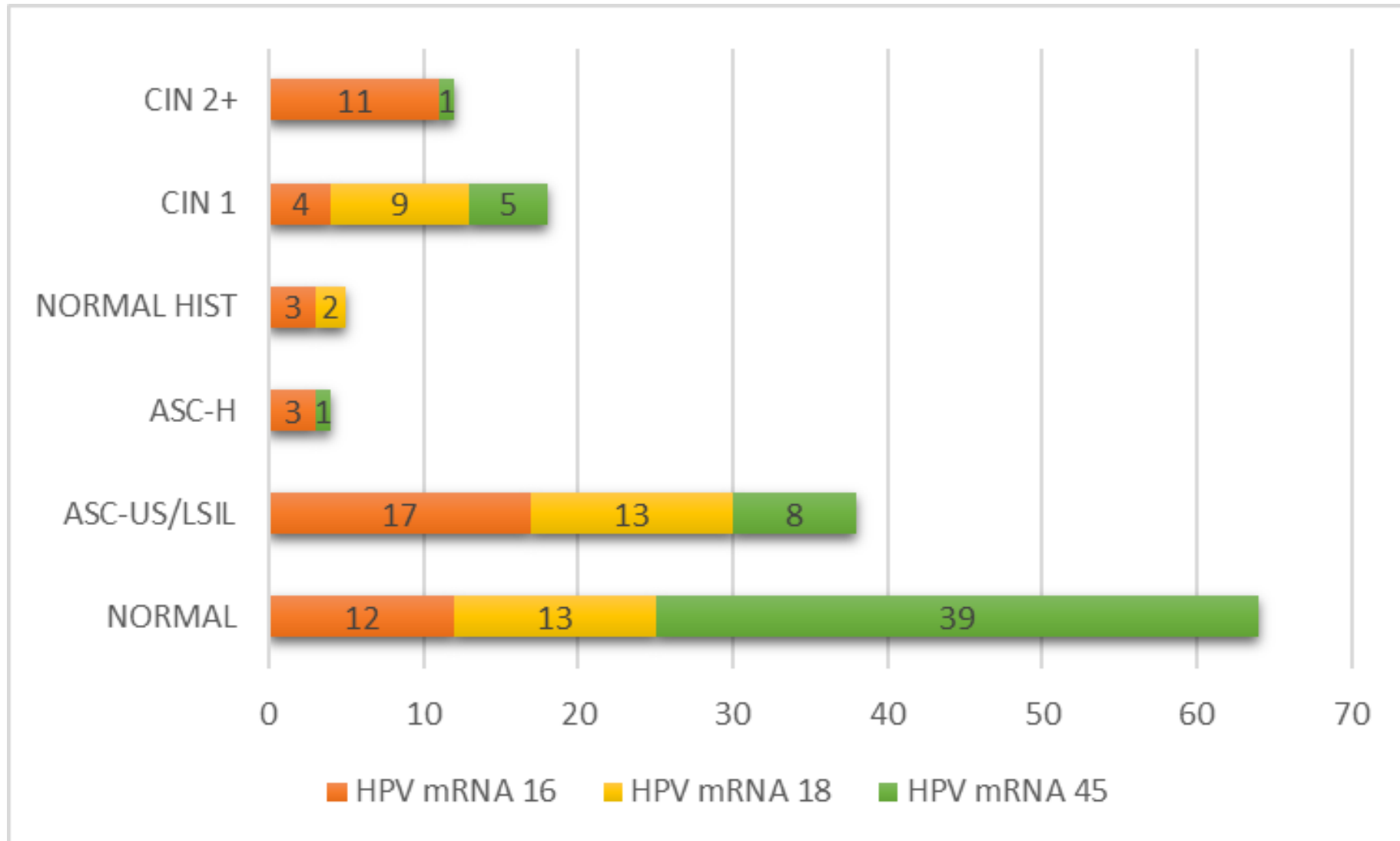
Histology Results pr. Aug 2017

PreTect SEE: **34.3%** PPV for CIN2+ (12/35*)



*Biopsies received from 35/42 women with revised cytology

HPV genotype distribution in Revised Cytology (n 106) and Histology (n 35)



Conclusions:

- We increased detection rate of CIN2+
- PPV= 34.3% (CIN2+)
- HPV mRNA 16 in 92% of CIN2+
- Only 0.9% of all normal PAP smears required rescreening
- Improved screening sensitivity without excessive workload is possible

Ongoing project: Continuous data flow

- Sept 2017: 38,000 samples currently tested with PreTect SEE; Number of women with CIN2+ still increasing
- 2019: 100,000 women to be included
- Low positivity rate makes the 3-type HPV mRNA test suitable even in young women < 34 yrs
- Identifying more women at 1. screening round will prevent more women from developing cancer within next screening interval
- Estimated annual reduction of 3-4 cases of CxCa in Troms and Finnmark counties

THANK YOU!

