

Background

Gastroenteritis is a leading cause of death worldwide across all age groups. It is estimated that 1.31 million people died from diarrheal disease in 2015. The BioCode® Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid test intended for the simultaneous detection and identification of 17 targets (Table 1). The BioCode® GPP is an FDA-cleared panel that has been validated with KingFisher Flex (ThermoFisher), easyMAG (bioMerieux), and MagNA Pure 96 (Roche) systems. This is an observational statistical analysis of five years of BioCode® GPP testing data at Path AI Reference Laboratory (now Quest Diagnostics, Memphis), using the MagNA Pure 96 as the extraction method. Rectal and fecal swabs are not a validated sample type with the BioCode® GPP and were validated independently at Path AI Reference Laboratory.

Table 1. Organisms Detected by the BioCode® Gastrointestinal Pathogen Panel.

Bacteria	
• <i>Campylobacter</i> spp.	• Shiga toxin-producing <i>E. coli</i> (STEC)
• <i>Clostridium difficile</i> toxin A/B	• <i>E. coli</i> O157
• <i>Salmonella</i> spp.	• <i>Vibrio parahaemolyticus</i>
• <i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)	• <i>Vibrio</i> spp.
• Enteroaggregative <i>E. coli</i> (EAEC)	• <i>Yersinia enterocolitica</i>
• Enterotoxigenic <i>E. coli</i> (ETEC)	

Viruses	Parasites
• Norovirus GI/GII	• <i>Cryptosporidium</i> spp.
• Adenovirus 40/41	• <i>Entamoeba histolytica</i>
• Rotavirus A	• <i>Giardia lamblia/intestinalis</i>

Methods

Retrospective data was abstracted from electronic records of patient samples tested with BioCode® GPP at Path AI Reference Laboratory. Data was analyzed and summarized as follows:

- Demographics (ages, genders, and geographic distribution)
- Assay Results (positive and negative rates, coinfection rates, positives by pathogens and sample types, and invalid rates)

Results

A total of 82,032 patients from 49 states were tested with the BioCode® GPP at Path AI Reference Laboratory from April 2019 to March 2024. Female and male patients were 67% and 33%, respectively. Patients were grouped via the following age brackets: 0–5 years (2%), 6–21 years (6%), 22–59 years (43%), and 60+ years (49%). The corresponding positive rates were 49% for ages 0–5, 20% for ages 6–21, 17% for ages 22–59, and 16% for ages 60 and older. Sample types were fresh stool (78%), rectal swab (15%), and fecal swab (7%). The positive rates of fresh stool, fecal swabs, and rectal swabs were 17%, 17%, and 21%, respectively. Eighteen percent of patients were positive for at least one target, of which 57% were *C. difficile* positives. Of positive patients, 8% were positive for more than one target. Internal control (IC) invalid rates due to inhibitory samples were 4.5%, 0.7%, and 0.4% for fresh stool, rectal, and fecal swab, respectively.

Conclusions

The BioCode® GPP testing data from April 2019 to March 2024 offers key insights into patient demographics and results. The panel was used to test patients from 49 states, with twice as many individuals identified as female versus male at birth. While more than 90% of patients were older than 22, children aged five and under had over twice the positivity rate of all other age groups. Eighteen percent of patients tested positive for at least one target. Both rectal and fecal swabs were valid sample types. Fresh stool and fecal swabs exhibited equivalent positivity rates, whereas rectal swabs showed a higher positivity rate than the other sample types. *C. difficile* emerged as the leading cause of gastroenteritis, responsible for more than half of all positive results. Additionally, rectal and fecal swabs both demonstrated lower invalid rates compared to fresh stool when evaluated on the BioCode® GPP.

Overall Positive Rate and Coinfection Rate

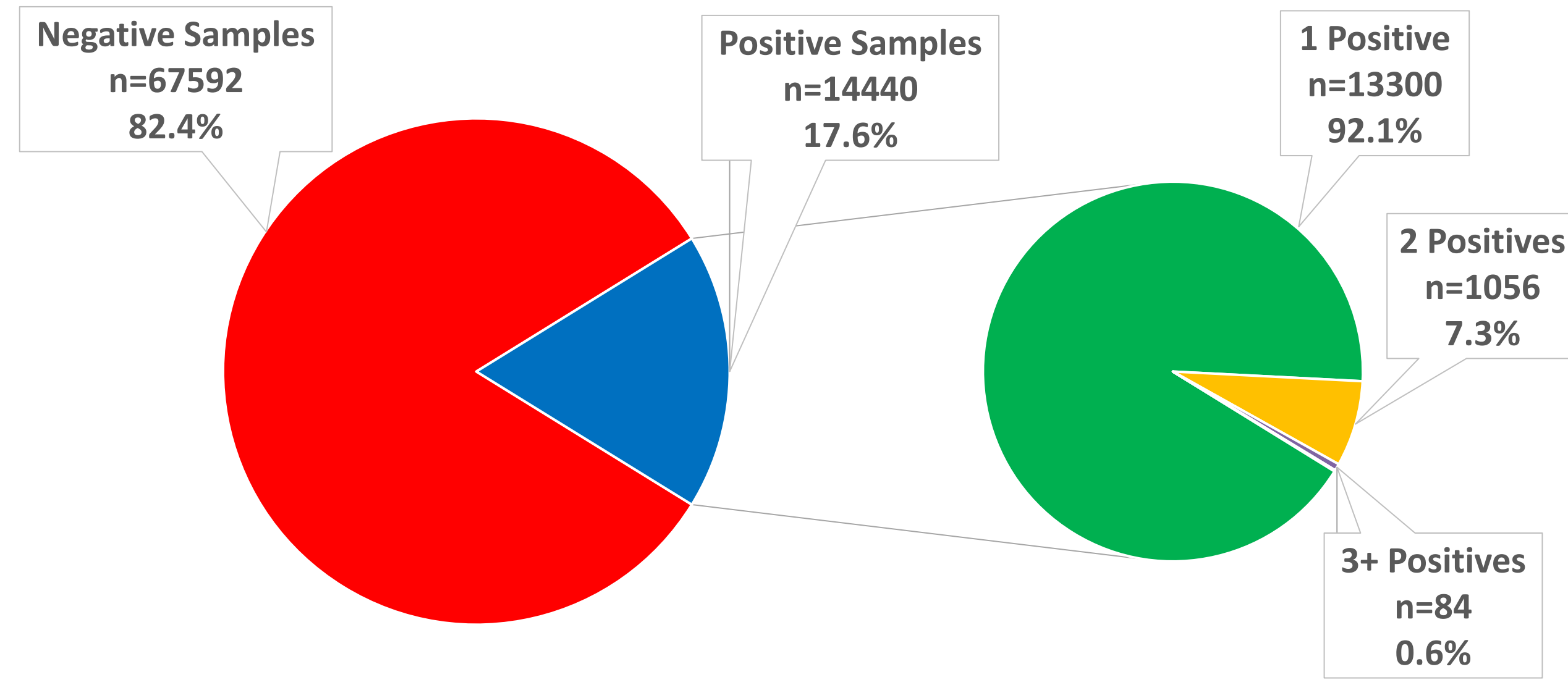


Figure 1. Overall Positive Rate and Coinfection Rate

Of 82,032 total samples 14,440 were positive for at least one target for an overall positivity rate of 17.6%. Of all 14,440 positive samples, 1,140 were positive for 2 or more targets for a coinfection rate of 7.9%.

Positives per BioCode® GPP Target

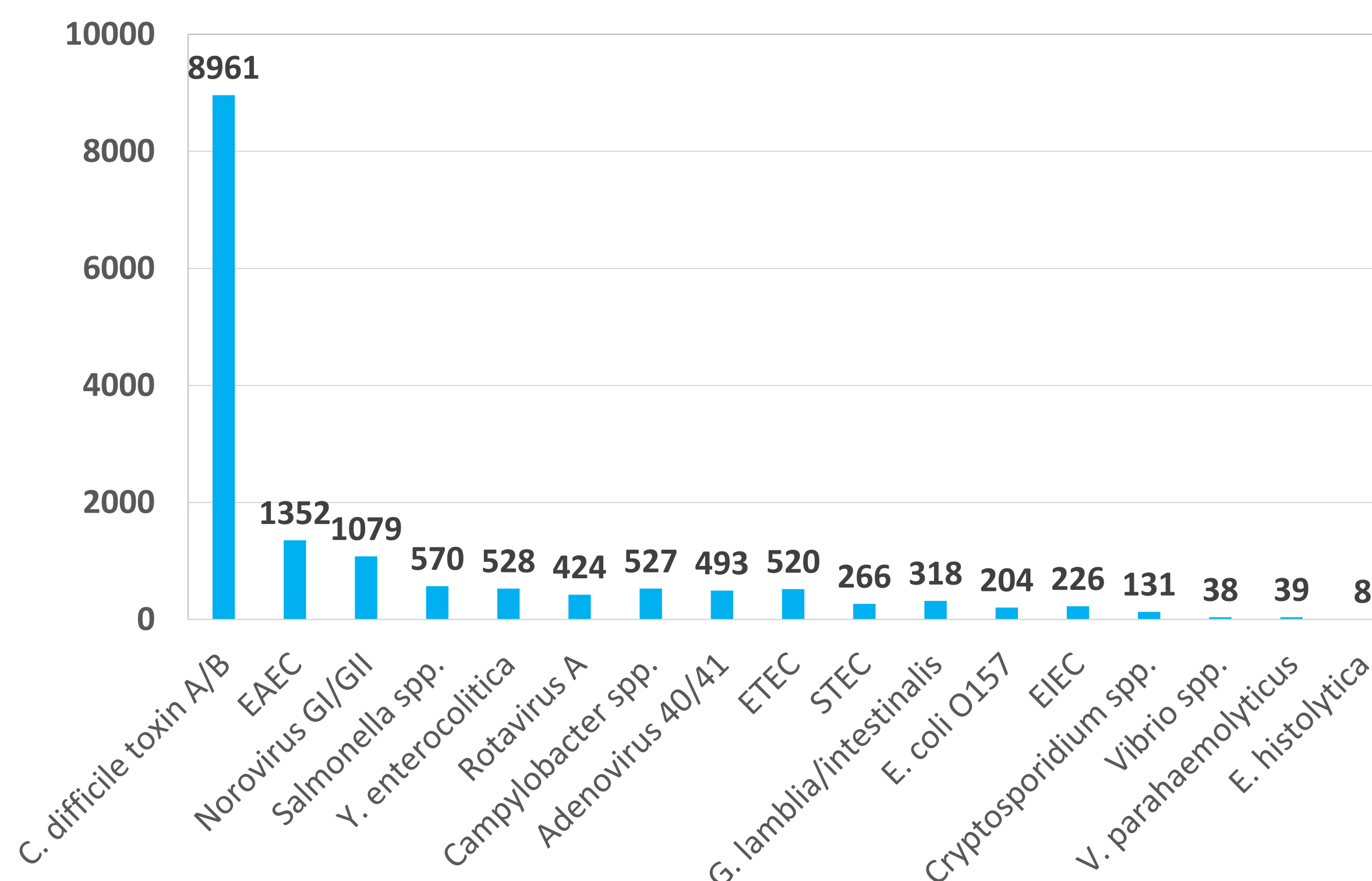


Figure 2. Positives Detected per BioCode® GPP Assay

The most common target detected via the BioCode® GPP was *C. difficile* with 8,961 positive samples recorded (57%). All targets on the BioCode® GPP were detected at least once.

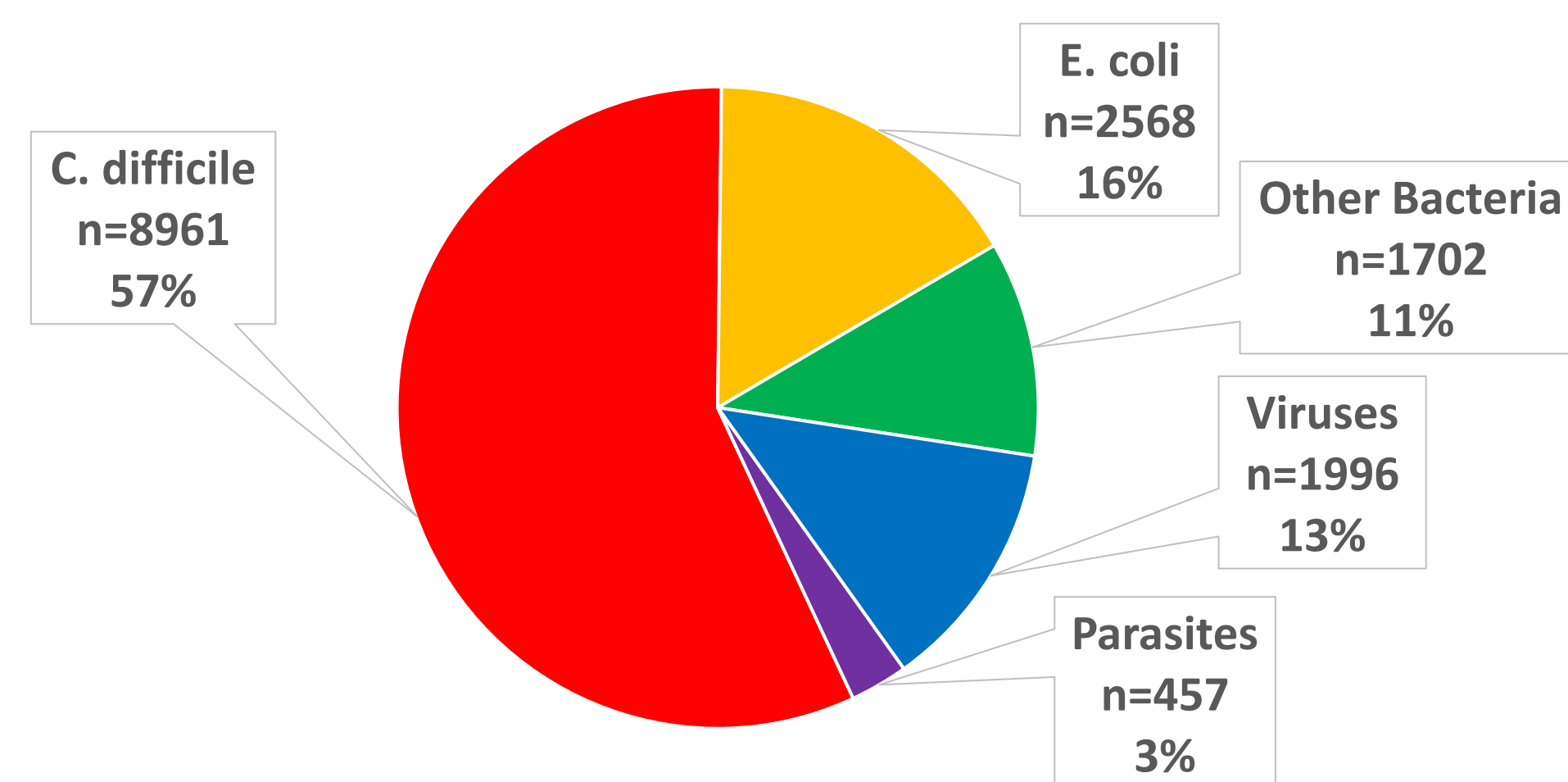


Figure 3. Relative Frequency of Targets Detected

Targets were grouped into 5 categories to compare the relative frequency of positive samples.

Frequency, Positive Rates, and Invalid Rates per Sample Type

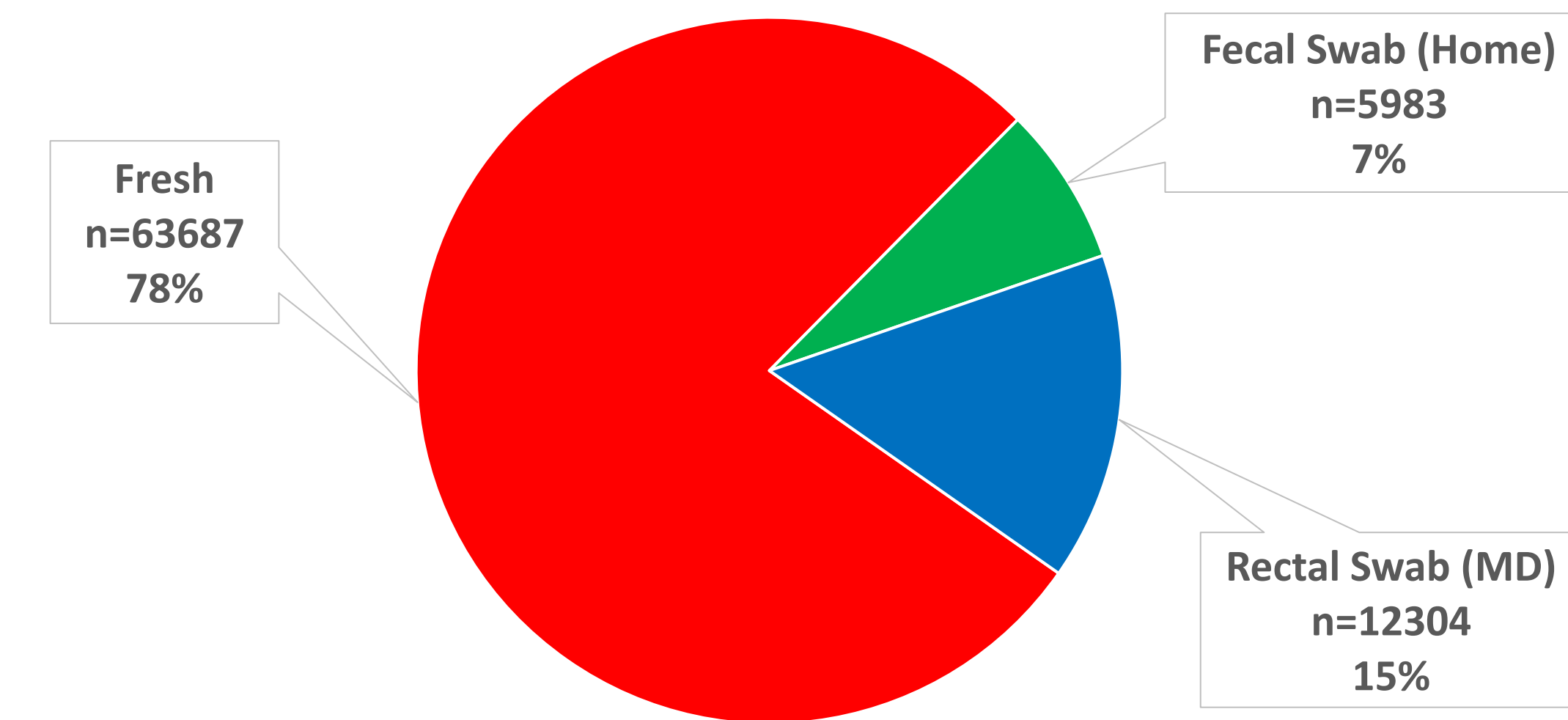


Figure 4. Sample Types Tested

Sample types tested were fresh stool (78%), rectal swabs collected at a clinical site (15%), and fecal swabs collected via a home collection kit (7%).

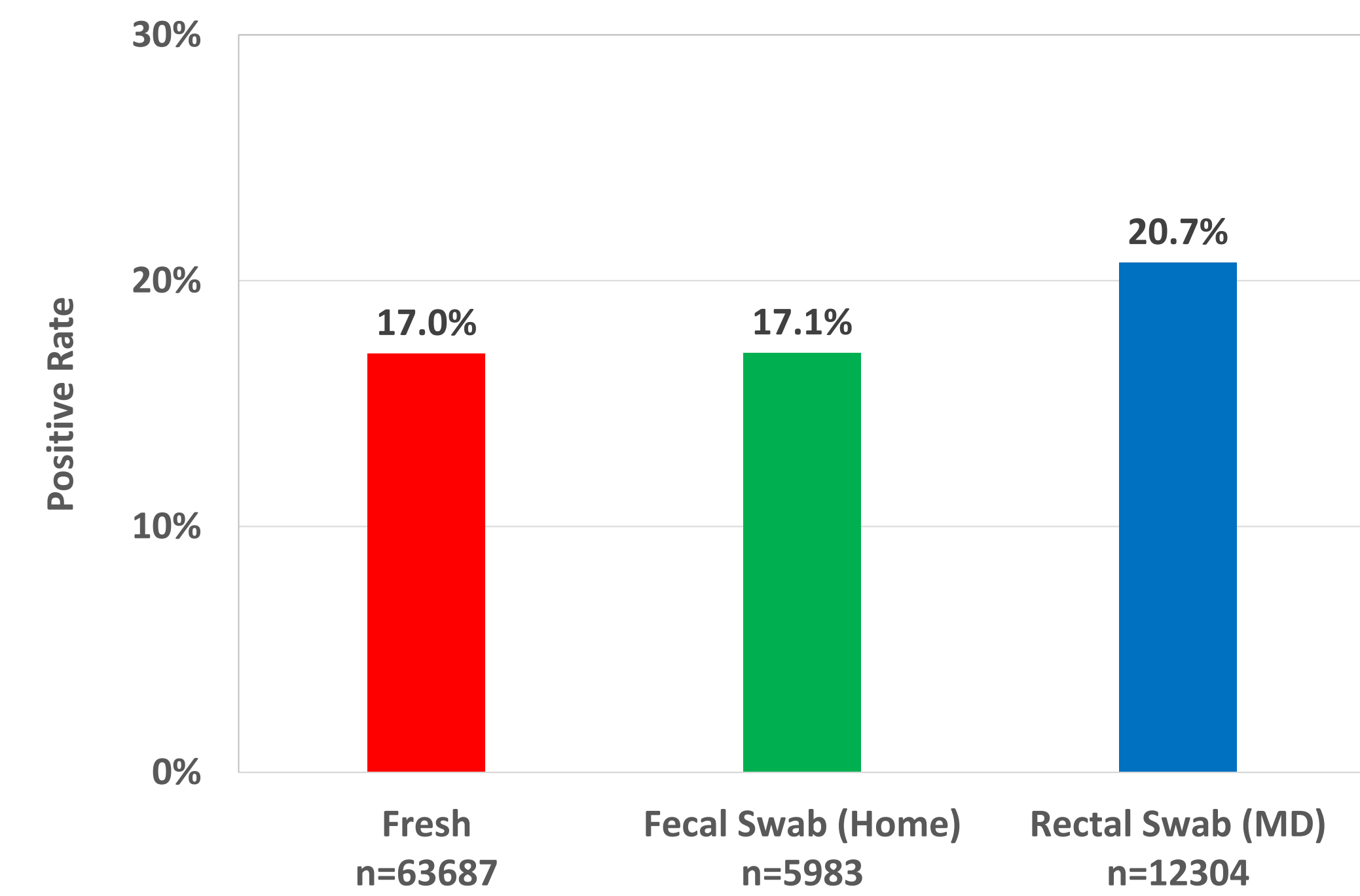


Figure 5. Positive Rates per Sample Type

The positive rates of Fresh Stool, Fecal and Rectal swabs were 17%, 17%, and 21%, respectively. The positive rate of Rectal Swab (MD) compared to Fresh Stool was significantly higher by 3.75% (Two-Sample Proportion Z-Test, P<0.001).

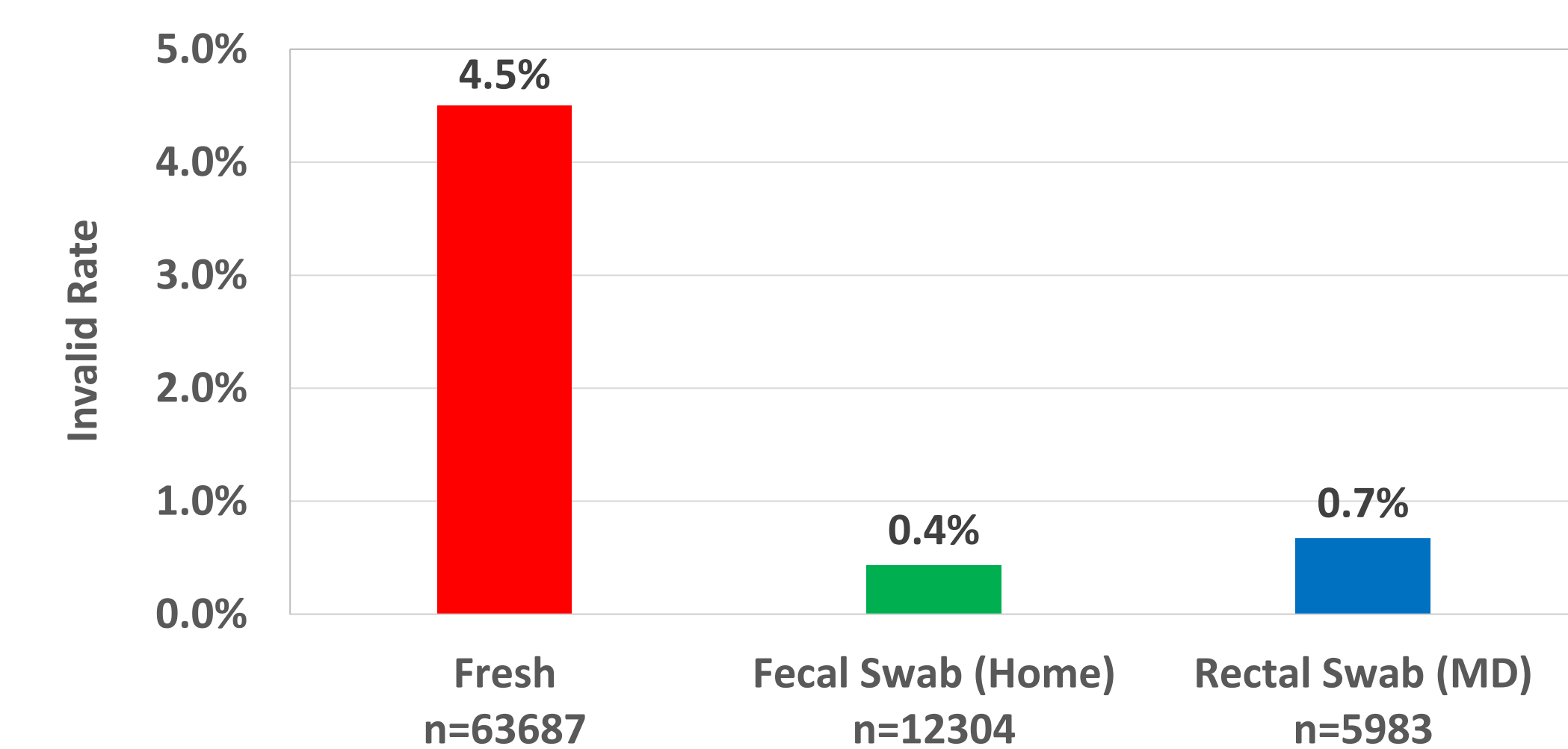


Figure 6. Invalid Rates per Sample Type

Internal control invalid rates due to inhibitory samples were 4.5%, 0.7%, and 0.4% for fresh stool, rectal, and fecal swab, respectively.

Geographic Distribution of Patients

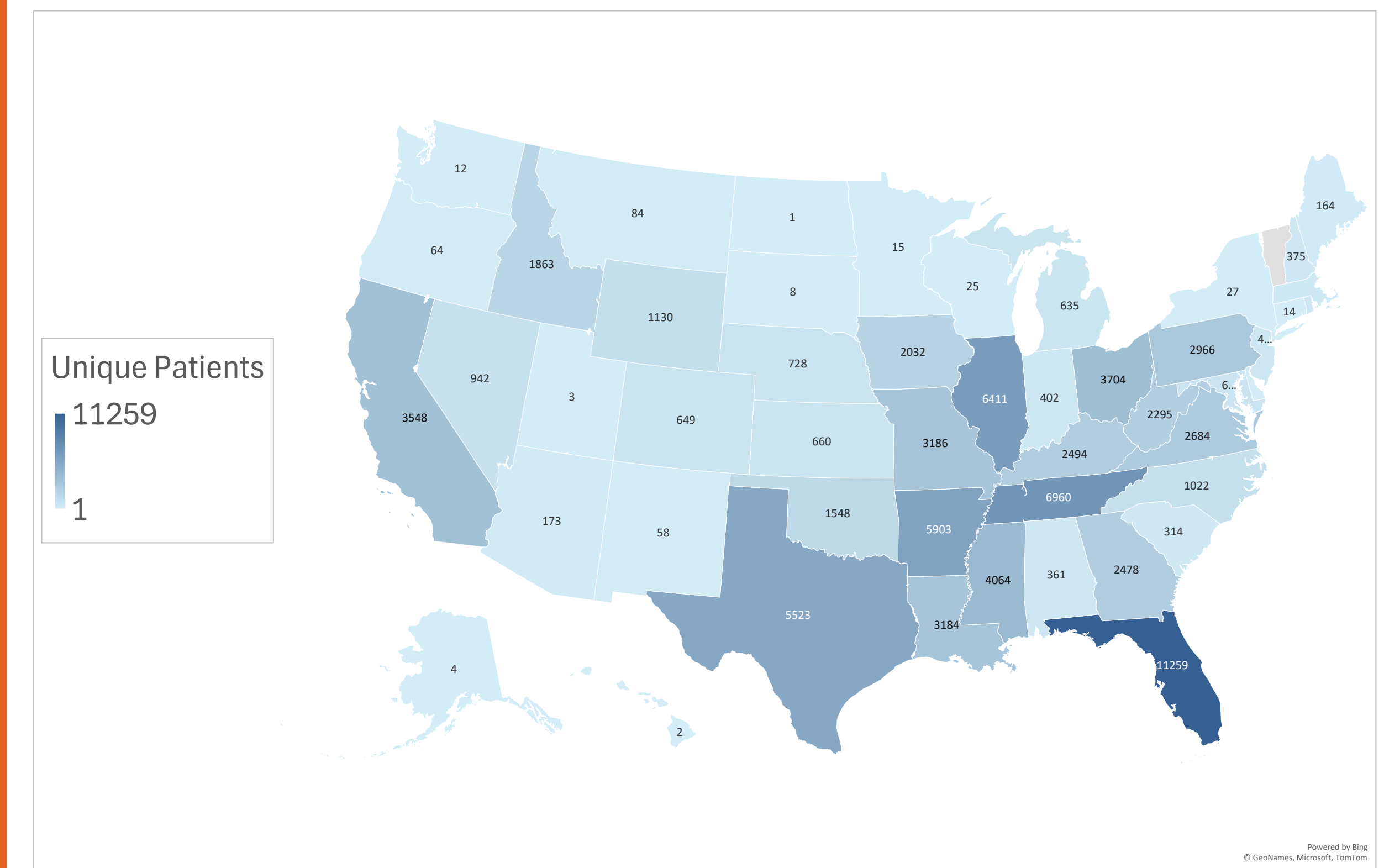


Figure 7. Geographic Distribution of Patients

Unique patient samples were tested from 49 states with a bias towards the southeast geographic region. Florida recorded the highest number of unique patients at 11,259 (13.7%).

Patient Demographics and Positive Rates by Age

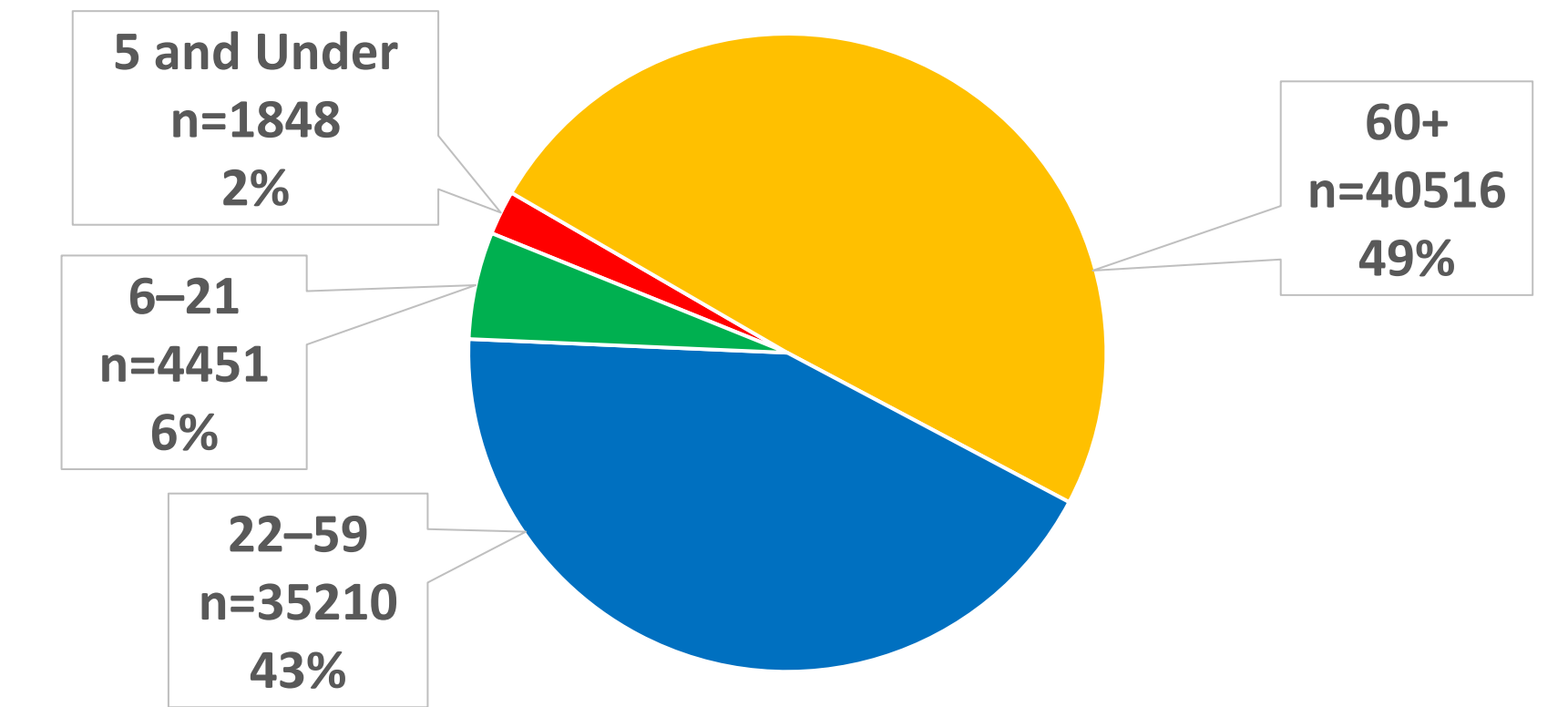


Figure 8. Patient Demographics by Age Bracket

Patients were grouped via the following age brackets: 0–5 years (2%), 6–21 years (6%), 22–59 years (43%), and 60+ years (49%).

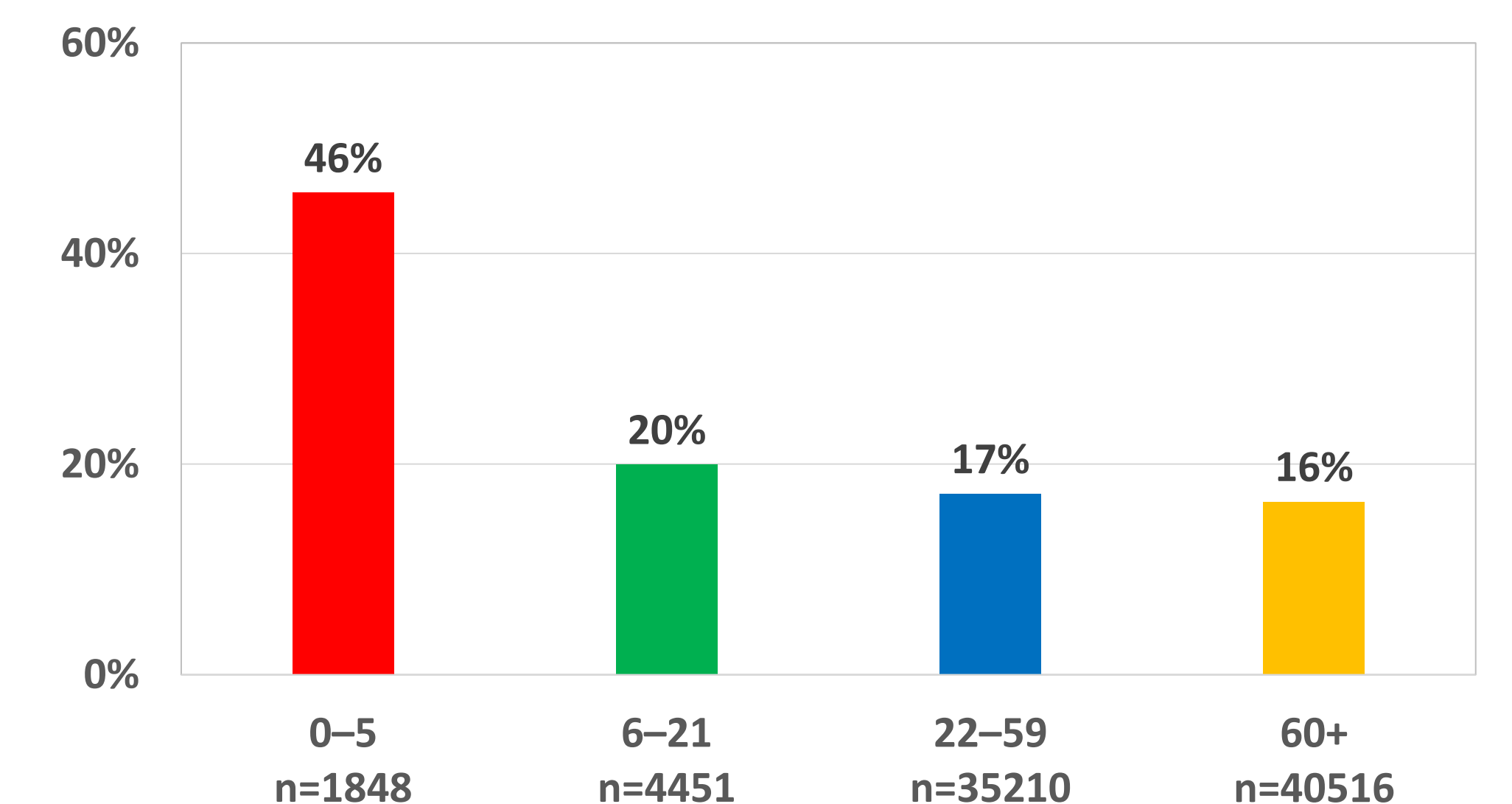


Figure 9. Positivity Rate by Age Bracket

The positive rates for patients aged 0–5, 6–21, 22–59, and 60+ years were 49%, 20%, 17%, and 16% respectively.