Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Evidence Summary for COVID-19 Clinical Samples

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The Health Information and Quality Authority (HIQA) has developed a series of 'Evidence Summaries' to assist the Clinical Expert Advisory Group (EAG) in supporting the National Public Health Emergency Team (NPHET) in their response to COVID-19. These summaries are based on specific research questions. This evidence summary was developed to address the following research question:

> **For individuals who have COVID-19, what clinical samples and collection sites are suitable for SARS-CoV-2 testing?**

The processes as outlined in HIQA's protocol were followed. Below is the summary of all relevant evidence from 30 December 2019 until 03 April 2020.

Results

We identified 28 studies, one cohort study, one cross-sectional study and 26 case series.[1] The majority of studies (n=22) were from China, two were from Singapore,[2, 3] with one each from the US,[4] South Korea,[5] Hong Kong,[3] and Germany.[6] Study sizes ranged from 2 to 213 patients. Five of the 28 studies reported the exact number of specimens examined, ranging from 108 to 804.[4, 7-9] Twenty-two of the 28 studies included patients with confirmed COVID-19. Seventeen of these 22[2-18] studies included patients with laboratory-confirmed COVID-19 (with 12[2, 4-7, 10, 13-15, 17] studies specifying respiratory swabs were used for confirmation). Two studies included a mix of laboratory-confirmed and clinically-confirmed (e.g. CT scans) cases,[19, 20] while three studies did not explicitly describe how a diagnosis was established.[21-23] All these 22 studies compared different types of clinical samples (e.g. sputum, urine) using a PCR test for the detection of SARS-CoV-2. Three of the 28 studies included patients with suspected COVID-19 and compared SARS-CoV-2 detection rates using different sample sites.[24-26] One of the 28 studies included recovered patients, and compared SARS-CoV-2 detection rates from different samples during convalescence.[27] Two of the 28 studies investigated familial clusters.[28, 29] The majority of studies obtained serial samples from patients over time, and tested samples at varying time points throughout the disease progression.

Concordance

Concordance rates between samples collected from different specimen sites in an individual were reported in five studies.

Two studies looked at concordance between throat swabs and sputum samples with Lin et al.[25] reporting 52% concordance in 54 suspected cases. The positive rates of SARS-CoV-2 from sputum specimens was 77% (n=40) and 44% (n=23) for throat swabs. Positive sputum with negative throat swabs were reported in 40% and

positive throat swabs with negative sputum were reported in 8%. Woelfel et al.[6] reported five out of seven paired samples had similar virus concentrations.

Comparing the results from five cases of throat swabs and bronchoalveolar lavage fluid (BALF) samples collected at the same time, Liu et al.[11] found positive results from BALF samples and negative results from throat swabs in three cases, concluding that BALF was a more reliable sample.

In a comparison between lingual and throat swabs across two hospitals, Ye et al.[26] reported that in one hospital all (17/46) positive lingual swabs also had positive throat swabs and in the second hospital, 45% (10/22) of positive lingual swabs also had positive throat swabs.

Comparing pharyngeal and stool samples collected and tested on the same day in eight patients, Lu et al.[22] reported that there was more concordance with N gene testing (7/8), than with ORF1ab testing (3/8).

Positive detection rates

Twenty-seven studies reported on positive detection rates across sites (including sputum, faecal, urine, blood, saliva, lingual, ocular, BALF and vaginal) in patients with laboratory-confirmed COVID-19, as per oropharyngeal and nasopharyngeal swabs.

Sputum samples showed a high positivity rate, ranging from 77% to 100% across six studies.[4, 6, 8, 23, 25, 28] However, it should be noted that studies reporting 100% detection rates were based on samples of two and four patients.

Faecal samples were reported to be positive in a range of 3% to 100% of samples across 12 studies.[2, 3, 7, 8, 10, 12, 15-19, 24, 25] However, it should be noted that the 100% detection rate was based on a study with three children. Five studies reported no positive detection.[5, 6, 23, 28, 29] Seven of the twelve positive studies reported that stool samples remained positive for longer than oropharyngeal and nasopharyngeal samples.[6, 7, 10, 15, 16, 25, 27] For example, Jiang et al.[7] reported that 16 patients had positive stool samples after two consecutive negative pharyngeal swabs during hospitalisation. Ling et al.[27] also reported that in convalescent patients, clearance of viral RNA in stool samples was delayed compared with oropharyngeal swabs (median delay of 2 days).

Urine samples were reported in 14 studies with 11 of these reporting no positive detection,[2, 4-6, 8, 10, 21, 23, 24, 28, 29] and three reporting positive detection,[12, 14, 27] but at very low rate (7%-11%).

Detection in blood samples was included in 14 studies.[2, 3, 5, 6, 8, 10, 12, 17, 18, 21, 24, 27-29] Seven studies described the sample as blood, six of which reported positive detection rates ranging from 1% to 87%.[2, 3, 8, 12, 18, 21, 24] Seven studies described the sample as serum, with no virus detected in four studies[6, 10, 27, 29]; positive

detection was reported in three studies, at rates ranging from 17%-50.[5, 17, 28] No positive detections were reported in one study that used plasma samples.[5]

Saliva was analysed in two studies, with positive detection rates of between 78% and 92%.[3, 21]

One study reported that the positive rate of throat swabs (44%) was higher than that of lingual swabs (36%) in suspected cases.[26]

Three studies examined ocular samples. SARS-CoV-2 was found in ocular discharges in a single patient in a cross-sectional study of 72 patients[13] and in two of 38 patients in a second study.[20] The third study reported that tear samples in five out of 32 cases were positive.[21]

Two studies reported on BALF and reported positive findings of 79% and 100%, with variation noted across the timing of sample collection.[8, 28] As these samples were obtained from severely ill patients only, the sample sizes were considerably lower than other studies (all less than 15 patients).

One study examined vaginal swabs and found no positive RT-PCR results.[19]

In one small study of a familial cluster, COVID-19 was detected in throat swabs taken in pre-symptomatic patients, but was not detectable in serum, stool, urine or urine samples.[29]

Sample adequacy and test spoilage

Data on sample adequacy and test spoilage were not reported on specifically in any of the included studies. No study reported data comparing independent testing at the same site, which would facilitate analysis of sampling errors.

Study quality and quality of the evidence

The included studies were of low to moderate quality for their design (case series); nine studies[4, 7, 12, 13, 16, 19, 22, 25] were pre-prints, from a non peer-reviewed journal, raising additional concerns about their quality. The majority of studies had small sample sizes and the identification and selection of cases for inclusion was not always adequately described. Specific details regarding the PCR test (e.g. gene targets, threshold values) were poorly reported across studies, as was the number of specimens collected from each site. Given the timeframes of reporting, and the lack of reporting of patient demographics in some papers, it is difficult to determine if some patients were included in more than one study, from the same region (for example Wuhan, China).

Discussion and conclusion

The level of evidence on clinical samples and collection sites suitable for SARS-CoV-2 testing overall is low. The limited number of case series identified mainly included

patients with laboratory-confirmed COVID-19, as per PCR testing of oropharyngeal and nasopharyngeal swabs. From this review, there is limited evidence reporting concordance between different samples sites and specimens within individuals. There are challenges in identifying evidence on sample adequacy as none of the studies reported comparisons between independent tests taken at the same site.

There is inconsistent detection of SARS-CoV-2 in other specimen sites reported in these studies. Sputum and faecal samples returned more positive tests than samples from other sites (e.g. blood, urine), but the reported ranges are large, particularly for faecal samples, which may stay positive for longer over the disease course. It is unclear from included studies, if this represents ongoing infectious disease or shedding of inactivated viral material. Sputum demonstrated less variation in terms of the range of positive findings, across six studies with small sample sizes. However, the use of sputum may be limited because not all patients with SARS-CoV-2 produce sputum.

While acknowledging the limited quantity and quality of data in this review, it would appear that urine, conjunctival, serum and blood samples do not appear to be reliable samples for detection of SARS-CoV-2 with typically low rates of detection. There is variation in the timing across the studies, in terms of when samples were taken and it is therefore difficult to ascertain which samples perform best, at which time points in the disease trajectory. In particular, faecal samples tended to be positive later in the disease course and BALF is only positive in more seriously ill patients with evidence of lower respiratory tract symptoms.

There may be a number of explanations for any apparent discordance between test results based on different specimens and or discordance between test results and clinical findings which are unrelated to the test itself. Firstly, there is a potential for pre-analytical errors including issues such as insufficient sampling, contamination of specimens, and inappropriate storage and transport conditions. Secondly, the analytical process can effect results with the use of different sample preparations and varying levels of analyst skills. Thirdly, the viral dynamics of SARS-CoV-2 across the time course of the infection are still not fully understood. Hence, false negative test results may occur if samples are tested during the early incubation period or else during the late convalescent phase, when virus levels may be undetectable.

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Table 1 Summary of identified studies

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Cai[10] **China (Wuhan)** **Case series** **DOI:** https://doi.org/10.1093/cid/ciaa198	**Population setting:** 10 patients admitted to a Children's Hospital with laboratory confirmed COVID-19 (upper respiratory tract samples). **Demographics:** *Age:* 3-131 months (mean: 74 months) *Sex:* Male 4, female 6 **Clinical characteristics:** *Presentation:* Fever 8 (80%); cough 6 (60%); sore throat 4 (40%); stuffy nose 3 (30%); sneezing and rhinorrhea 2 (20%).	**Sample site(s):** Nasopharyngeal, Throat, faecal in 6 patients, urine and serum in 5 **Test:** rRT-PCR **Thresholds:** Ct < 35 = positive **Gene Targets:** N, ORF	**SARS-CoV-2 detection rate** Nasopharyngeal and throat: 10/10 (100%) Faecal: 5/6 (83.3%) (the negative swab was obtained 10 days after illness onset) Urine: 0/5 (0%) Serum: 0/5 (0%) [NP/throat swab taken 4-48 hours after illness onset, faecal sample 3-13 days after onset, urine and serum 2-3 days after onset] **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported
Chan[28] **China (Wuhan)** **Case series** **DOI:** https://doi.org/10.1016/S0140-6736(20)30154-9	**Population setting:** Familial cluster of 6 hospitalised patients - 5/6 laboratory confirmed COVID-19. **Demographics:** *Adults:* 5 *Children:* 1 *Age:* 36–66yrs; 10yrs (child) *Sex:* Male, 3 (50%); Female 3 (50%) **Clinical characteristics:** *Presentation:* Fever, 5 (83%); Cough, 4 (67%) (3 dry, 1 productive); Generalised weakness, 3 (50%); Nasal congestion, 1 (17%); Rhinorrhoea, 1 (17%); Sneezing, 1 (17%); Sore throat, 1 (17%); Pleuritic chest pain, 1 (17%); Diarrhoea, 2 (33%)	**Sample site(s):** Nasopharyngeal, throat, stool, urine, serum, sputum **Test:** RT-PCR (conventional and real time) **Thresholds:** NR **Gene Targets:** S	**SARS-CoV-2 detection rate** Respiratory: 5/6 (83%) (positive for S gene by both PCR methods) (The negative swab was collected 7 days after symptom onset) Serum: 1/6 (17%) Urine: 0/6 (0%) Faecal: 0/6 (0%) Sputum: 2/2 (100%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** Sputum samples were available for testing from 2 patients only. The cycle threshold values of the sputum samples were 8–13 cycles earlier than those of throat swabs, indicating higher viral loads detected in the lower respiratory tract.

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Cui[19] **China (Wuhan)** **Case series** **DOI:** https://doi.org/10.1101/2020.02.26.20028225	**Population setting:** 35 hospitalised patients - 27 with laboratory confirmed COVID-19 (respiratory samples), 8 with clinical diagnosis (epidemiological history, symptoms and chest CT). **Demographics:** *Adults:* 35 *Age:* Mean 61.5yrs (SD 11.2yrs) *Sex:* Female (100%) **Clinical characteristics:** *Presentation:* Fever, 25 (71%); Muscle ache, 4 (11%); Cough, 4 (11%); Fatigue, 1 (3%); Shortness of breath, 1 (3%).	**Sample site(s):** Throat, anal, vaginal **Test:** rRT-PCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Throat: 27/35 (77%) Anal: 1/35 (3%) Vaginal: 0/35 (0%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** Vaginal discharge, exfoliated cell and anal swab samples were collected about one week after diagnosis.
Fang[21] **China (Xiangtan)** **Case series** **DOI:** https://www.sciencedirect.com/science/article/pii/S0163445320301390	**Population setting:** 32 hospitalised adults (8 ICU and 24 non-ICU patients) with COVID-19 **Demographics:** *Age:* Median, 41 Range: 34-54 *Sex:* Male, 16 (50%), Female, 16 (50%) **Clinical characteristics:** *Presentation:* Cough, 24 (75%), fever, 17 (53%), fatigue 5 (15.6%), headache, 6 (18.8%), diarrhoea 3 (9.4%), sore throat 7 (21.9%) muscular soreness, 6 (18.8%) no symptoms, 4 (12.5%)	**Sample site(s):** Nasal, blood, faecal, urine, saliva and tears. **Test:** rT-PCR **Thresholds:** NR **Gene Targets:** NR	**SARS-CoV-2 detection rate** Nasal: 32/32 (100%) Saliva: 25/32 (78.1%) Tears: 5/32 (15.6%) Urine: 0/32 (0%) Blood: 7/8 (87.5%) ICU patients, 16/24 (66.7%) non-ICU patients Faecal: not reported **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** The nucleic acid conversion time (from positive to negative) of SARS-CoV-2 of nasal swabs was significantly longer than that of blood (p=0.000) and saliva (p=0.05).

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Jiang[7] **China (Zhuhai)** **Retrospective case series** **DOI:** https://doi.org/10.1101/2020.02.25.20027755	**Population setting:** 87 COVID-19 (pharyngeal RT-PCR and chest CT) patients from a single hospital from a population of 568 patients. **Demographics:** *age:* 0-14: 5 (71.4%) 15-49: 44 (50.6%) 50-64: 25 (28.7%) ≥65: 13 (14.9%) *Gender:* male 40/87 (45.9%) **Clinical characteristics:** *Presentation:* Mild: 73 (83.9%) Severe: 14 (16.1%)	**Sample site(s):** Pharyngeal and nasal swabs (623), stool (181) **Test:** RT-PCR **Thresholds:** Positive: Ct value < 37 **Gene Targets:** RdRp, E, N	**SARS-CoV-2 detection rate** Cases with stool nucleotide detection: 75 At least one positive result: 35/75 (46.7%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** The stool presented earlier positive than the throat swab in 2 cases. 16 patients had positive results from stool after two consecutive negative results of pharyngeal swabs during hospitalisation.
Kim[5] **South Korea** **Case series** **DOI:** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7036338/pdf/jkms-35-e86.pdf	**Population setting:** 2 hospitalised patients with laboratory confirmed COVID-19 (URT). **Demographics:** Adults *Patient 1:* 35 year old woman *Patient 2:* 55 year old man **Clinical characteristics:** *Presentation*: Patient 1: fever, chills, and myalgia Patient 2: sore throat and intermittent myalgia	**Sample site(s):** URT, LRT, (collected every day after the diagnosis) serum, plasma, urine, stool (collected sequentially) **Test:** rRT-PCR **Thresholds:** Ct > 37 = negative **Gene Targets:** RdRp, E	**SARS-CoV-2 detection rate** Upper respiratory tract: 2/2 (100%) Lower respiratory tract: 2/2 (100%) Serum: 1/2 (50%) Plasma: 0/2 (0%) Urine: 0/2 (0%) Stool: 0/2 (0%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Kujawski[4] **US** **Case series** **DOI:** https://www.medrxiv.org/content/medrxiv/early/2020/03/12/2020.03.09.20032896.full.pdf	**Population setting:** 12 patients with laboratory-confirmed (respiratory samples) COVID-19 (7 were hospitalised), 398 specimens. **Demographics:** *Age:* Median: 53 (Range 21-68) *Sex:* Male 8 (67%), Female 3 (33%) **Clinical characteristics:** *Presentation*: cough (n=8), fever (n=7), diarrhoea (n=1) and sore throat (n=1) *Severity:* mild to moderate	**Sample site(s):** NP, OP, (respiratory specimens illness days 1–9, median, day 4), sputum, serum, urine, stool (every 2–3 days for the first 17 days of illness) **Test:** rRT-PCR **Thresholds:** NR **Gene Targets:** NR	**SARS-CoV-2 detection rate** Initial testing: NP: 10/12 (83%) OP: 11/11 (100%) Sputum: 4/4 (100%) All 12 patients had SARS-CoV-2 RNA detected in at least one NP swab, 11/12 in OP swab, 6/6 in sputum, 1/12 in serum, 7/10 in stool, and 0/10 in urine. **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** 98 pairs of simultaneous NP and OP specimens: 58 (59%) had concordant results. Among 27 discordant pairs with one positive specimen, the NP specimen was positive in 70%; the remaining 13 discordant pairs had one negative and one inconclusive specimen. Two patients provided sputum specimens when NP and/or OP specimens tested negative, and sputum continued to be positive in both patients.

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Lin[25] **China (Wuhan)** **Case series** **DOI:** https://doi.org/10.1101/2020.02.21.20026187	**Population setting:** 54 cases suspected of having COVID-19 in one hospital. **Demographics:** *Mean age (SD):* 57.3 years (SD 12.5) *Gender:* Male 27 (51.9%) **Clinical characteristics:** *Presentation:* NR	**Sample site(s):** Paired specimens of throat swabs and sputum **Test:** qRT-PCR **Thresholds:** Ct-value < 37 positive **Gene Targets:** ORF1ab, N	**SARS-CoV-2 detection rate** Throat swabs: 23 (44.2%) Sputum: 40 (76.9%) Sputum specimens showed a significantly higher positive rate than throat swabs in detecting viral nucleic acid using qRT-PCR assay (P=0.001). **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Same results in both swabs: 51.9% Both positive: 36.5% Both negative:15.4% Positive sputum, negative throat: 40.4% Negative sputum, positive throat: 7.7%
Ling[27] **China** **Case series** **DOI:** https://journals.lww.com/cmj/Fulltext/publishahead/Persistence_and_clearance_of_viral_RNA_in_2019.99362.aspx	**Population setting:** 66 COVID-19 patients admitted to hospital who recovered (recovered non-febrile patients without respiratory symptoms who had two successive (minimum 24 h sampling interval) negative RT-PCR). **Demographics:** *Mix of adults and children (predominantly adults)* Age: Median (IQR) 44 (34-62) Range: 16-78 *Sex:* Females, 28(42.4%); males 38 (57.6%) **Clinical characteristics:** *Presentation*: NR	**Sample site(s):** OP, stool, urine, and serum **Test:** RT-PCR **Thresholds:** NR **Gene Targets:** NR	**SARS-CoV-2 detection rate** Serum: 0/14 (0%) Urine: 4/58 (6.9%) Detection rate not reported for other samples, except that stool samples remained positive for longer than OP samples (positive stool detection in 54/66 cases with negative throat swabs). **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** 11 convalescent patients (16.7%) tested positive for viral RNA from stool specimens and 55 patients' stool specimens were negative for 2019-nCoV following a median duration of 11 (range 9–16) days after symptom onset. Among these 55 patients, 43 had a longer duration until stool specimens were negative for viral RNA than for throat swabs, with a median delay of 2 (range 1–4) days.

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Liu[11] **Case series** **China (Shenzhen)** **DOI:** http://dx.doi.org/10.1007/s11427-020-1643-8	**Population setting:** 12 laboratory confirmed COVID-19 from one hospital. **Demographics:** *Median age (range):* 62 (10 to 72) *Sex:* Male 8 (67%) **Clinical characteristics:** *Presentation:* fever 10, cough 11, myalgia 4, chill 5, nausea or vomiting 2, diarrhoea 2	**Sample site(s):** Throat swab, BALF collected from 10 patients **Test:** real-time PCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Not reported **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Throat swabs and BALF collected at the same time (n=5) Positive in both: 1 BALF positive, throat negative: 3 BALF negative, throat positive: 1
Lu[22] **China** **Case series** **DOI:** 10.1101/2020.03.24.20042689	**Population setting:** 36 patients, 108 clinical specimens. **Demographics:** *Age:* Not reported *Sex:* Not reported **Clinical characteristics:** *Presentation:* fever, coughing, or CT confirmed lung inflammation	**Sample site(s):** pharyngeal swab, stool and blood from different days during hospitalization **Test:** RT-PCR, digital (d)PCR **Thresholds:** Not reported **Gene Targets:** N, ORF1ab	**SARS-CoV-2 detection rate** Not reported **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** 8 patients had pharyngeal and stool samples collected and tested on the same day. 6 of these patients had blood tested also. *RT-PCR for ORF1ab* 8 positive pharyngeal samples, 3 positive in stool, blood all negative *dPCR for ORF1ab* 7 positive pharyngeal samples, 1 positive in stool, blood all negative *dPCR for N* 8 positive pharyngeal samples, 7 positive in stool, blood 2 positive

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Pan[23] **China** **Case series** **DOI:** http://www.sciencedirect.com/science/article/pii/S1473309920301134	**Population setting:** 2 patients admitted to hospital with COVID-19 (plus samples from 80 patients at different stages of COVID-19). **Demographics:** NR **Clinical characteristics:** NR	**Sample site(s):** Nasal, throat, sputum, urine and stool (serial samples collected daily after hospitalisation). **Test:** RT-PCR **Thresholds:** NR **Gene Targets:** N	**SARS-CoV-2 detection rate** For the 2 patients described separately: Throat: 2/2 Sputum: 2/2 Urine/Stool: 0/2 For the remaining patients: Stool: 9/17 (53%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Among the 30 pairs of throat swab and sputum samples available, viral loads were significantly correlated between the two sample types for days 1–3 (R^2=0.50, p=0.022), days 4–7 (R^2=0.93, p<0·001) and days 7–14 (R^2=0.95, p=0.028).
Peng[12] **China** **Case series** **DOI:** https://doi.org/10.1101/2020.02.21.20026179	**Population setting:** 9 patients with laboratory confirmed COVID-19. **Demographics:** *Age range:* 27 to 63 *Gender:* Male 4, female 5 **Clinical characteristics:** *Presentation:* fever (9); cough (6); sputum (3); sore throat (3); fatigue (2); diarrhoea (1)	**Sample site(s):** Oropharyngeal swab, blood, urine, anal swab **Test:** qRT-PCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Oropharyngeal swab: 7 (78%) Blood: 2 (22%) Urine: 1 (11%) Anal swab: 2 (22%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** One patient positive in both urine and oropharyngeal swab on day 7 after symptom onset. 2 patients had negative results in oropharyngeal swab, on the day 10 and 15 after onset. One patient three positive results in blood, anal swab and oropharyngeal swab on day 3 after onset.

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Sun[13] **Cross-sectional** **China** **DOI:** https://doi.org/10.1101/2020.02.26.20027938	**Population setting:** 72 patients with laboratory confirmed SARS-COV-2 (oropharyngeal swabs PCR). **Demographics:** *Mean age (SD):* 58.68 (14.81) *Sex:* 36 men (50%), 36 women (50%) **Clinical characteristics:** *Presentation:*	**Sample site(s):** Conjunctival swab. Sampling date varied from the day 6 to day 46, mean 18.15 days (SD 7.57). **Test:** RT-PCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Conjunctival swab: 1/72 **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Oropharyngeal swabs and conjunctival swabs: Both positive day 3 of hospitalisation Both negative day 10, 19 and 21 of hospitalisation.
To[3] **Hong Kong** **Cohort study** **DOI:** 10.1016/S1473-3099(20)30196-1	**Population setting:** 23 patients with laboratory-confirmed COVID-19 from 2 hospitals. NOTE: 12/23 reported on in previous To paper. **Demographics:** *Median Age (range):* 62 years (37 to 75) *Gender:* Female 10; male 13 **Clinical characteristics:** *Presentation:* fever 22 (96%), cough 5 (22%), chills 4 (17%), dyspnoea 4 (17%) *Severe:* 10, mild 13	**Sample site(s):** blood, urine, posterior oropharyngeal saliva, and rectal swabs **Test:** RT-qPCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Saliva: 20/23 (87%) Blood samples: 5/23 (22%) Rectal swabs: 4/23 (27%) *By severity:* ≥20 days in saliva: severe 4/8 (50%), mild 3/13 (23%) Blood: severe 3/10 (30%), mild 2/13 (15%) Rectal: severe 3/8 (38%), mild 1/7 (14%) Urine: severe 0/9 (0%), mild 0/9 (0%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Wang, L[14] **China (Wuhan)** **Case series** **DOI:** https://www.karger.com/Article/Pdf/507471	**Population setting:** 116 hospitalised, laboratory confirmed (throat swab) COVID-19 patients. **Demographics:** *Adults:* 116 (100%) *Age:* Median (IQR): 54 years (38-69) *Sex:* Male 67 (57.8%); Female 49 (42.2%) **Clinical characteristics:** *Presentation:* Mild pneumonia, 59 (50.8%); Severe pneumonia, 46 (39.7%); ARDS, 11 (9.5%)	**Sample site(s):** Throat, urine **Test:** RT-PCR **Thresholds:** Not reported **Gene Targets:** NP, ORF1ab	**SARS-CoV-2 detection rate** Throat swab: 116/116 (100%) Urine sediment: 4/53 (7.5%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** Of the four with positive SARS-CoV-2 in urine sample, RNA was positive in 3 patients and 1 patient was positive for SARS-CoV-2 ORF1ab.
Wang, W[8] **China (Hubei, Shandong provinces and Beijing)** **DOI:** 0.1001/jama.2020.3786	**Population setting:** 1,070 specimens collected from 205 inpatients with confirmed COVID-19 in 3 hospitals. **Demographics:** *Mean Age (range):* 44 (range, 5-67 years) *Gender:* 68% male. **Clinical characteristics:** *Presentation:* Most of the patients presented with fever, dry cough, and fatigue; *Severity:* 19% had severe illness	**Sample site(s):** Pharyngeal (either OP or NP) swabs, collected from most patients 1 to 3 days after hospital admission. Blood, sputum, faeces, urine, and nasal samples were collected throughout the illness. BALF was sampled from patients with severe illness or undergoing mechanical ventilation. **Test:** Real-time reverse transcriptase–polymerase chain reaction (rRT-PCR) **Thresholds:** <40 interpreted as positive **Gene Targets:** orf1*ab*	**SARS-CoV-2 detection rate** Pharyngeal swabs (n=398): 126 (32%) Sputum (n=104): 75 (72%) BALF (n=15): 14 (93%) Nasal swabs (n=8): 5 (63%) Faeces (n=153): 44 (29%) Blood (n=307): 3 (1%) Urine (n=72): 0 (0%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Woelfel[6] **Germany** **Case series** **DOI:** https://doi.org/10.1038/s41586-020-2196-x	**Population setting:** 9 cases (samples taken from inpatients) with confirmed COVID-19 diagnosed by RT-PCR from oral- or nasopharyngeal swab specimens. **Demographics:** "young- to middle-aged professionals" **Clinical characteristics:** *Presentation*: NR	**Sample site(s):** OP, NP, sputum, urine (27 samples), serum (31 samples), stool (13 samples). Samples taken during the clinical course in the hospital, as well as from initial diagnostic testing before admission. **Test:** qRT-PCR **Thresholds:** 10^2 copies/ml **Gene Targets:** E- and RdRp	**SARS-CoV-2 detection rate** OP: 9/9 (100%) NP: 9/9 (100%) (all taken between days 1 and 5) Sputum: not clear Urine: 0% Serum: 0% Stool: 0% **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Paired OP/NP swab and sputum samples taken at same time from 7 patients (2 and 4 days post-onset). Similar virus concentrations: 5 OP/NP swab samples had higher virus concentrations than sputum samples: 2 Sputum samples had higher virus concentrations than OP/NP swabs: 2
Wu, P[20] **China (Hubei)** **Case series** **DOI:** https://jamanetwork.com/journals/jamaophthalmology/article-abstract/2764083	**Population setting:** 38 hospitalised COVID-19 patients. **Demographics:** *Adults:* 38 (100%) *Age:* Mean (SD): 65.8 years (16.6) *Sex:* Male 25 (65.8%); Female 13 (34.2%) **Clinical characteristics:** *Presentation:* Data for patients with ocular manifestations only (n=12): Cough, 6 (50%); Expectorate, 3 (25%); Dyspnoea, 2 (17%); Chest tightness, 1 (8%)	**Sample site(s):** Nasopharyngeal and conjunctival **Test:** RT-PCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Nasopharyngeal: 28/38 (74%) Conjunctival: 2/38 (5%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Nasopharyngeal samples and conjunctival samples positive: 2/28 (7%) **Other findings of relevance:** n/a

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Wu, Y[15] **China** **Case series** **DOI:** https://doi.org/10.1016/S2468-1253(20)30083-2	**Population setting:** 74 hospitalised patients with RT-PCR (respiratory) confirmed COVID-19. **Demographics:** *Adults* Female 35 (47.3%) Male 39 (52.7%) Mean age 43.5 years **Clinical characteristics:** Cough, 37 (50.0%), fever, 45 (60.8%), dyspnoea, 9 (12.2%), snivel, 6 (8.1%), sore throat, 6 (8.1%), diarrhoea/vomit/stomach ache, 23 (31.1%)	**Sample site(s):** Throat, faecal Respiratory and faecal samples were collected every 1–2 days **Test:** Real-time RT-PCR **Thresholds:** NR **Gene Targets:** *RdRp*, *N*, *E*	**SARS-CoV-2 detection rate** Throat: 74/74 (100%) Faecal: 41/74 (55%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** Of 74 patients with faecal samples that were positive for SARS-CoV-2 RNA, respiratory samples remained positive for SARS-CoV-2 RNA for a mean of 16.7 days (SD 6.77) and faecal samples remained positive for a mean of 27.9 days (10.77) after first symptom onset.
Xie[24] **China (Sichuan)** **DOI:** 10.1016/j.ijid.2020.02.050	**Population setting:** 19 suspected cases from 2 hospitals. **Demographics:** *Median age:* 33 *Gender:* Female 58% **Clinical characteristics:** *Presentation:* fever 14; cough 13; fatigue 9; diarrhoea 2.	**Sample site(s):** Oropharyngeal swab, blood, urine and stool **Test:** RT-PCR (3 different 2019-NCoV Fluorescent RT-PCR Kits – GeneoDx, Maccura and Liferiver) **Thresholds:** Not reported **Gene Targets:** ORF1b, N	**SARS-CoV-2 detection rate** Oropharyngeal: 9 (47.4%) Stool: 8 (42.1%) Blood: 0 (0%) Urine: 0 (0%) *Note:* same result for each sample across the 3 kits. **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** 8/9 positive oropharyngeal samples were also positive in stool

<table>
<tr><th>Author
Country
Study design</th><th>Population setting
Patient demographics
Clinical characteristics</th><th>Test parameters</th><th>Primary outcome results</th></tr>
<tr><td>Xing[16]

China

Case series

DOI:
https://www.medrxiv.org/content/medrxiv/early/2020/03/13/2020.03.11.20033159.full.pdf</td><td>Population setting: 3 hospitalised children with laboratory confirmed COVID-19.
Demographics:
Case 1: 18 month old male
Case 2: 5 year old male
Case 3: 6 year old female
Clinical characteristics:
Presentation:
Fever, 3 (100%)</td><td>Test:
RT-PCR

Thresholds:
NR
Gene Targets:
NR

Sample site(s):
Throat and faecal</td><td>SARS-CoV-2 detection rate
Throat: 3/3 (100%)
Faecal: 3/3 (100%)

Adequate/sufficient sample
Not reported
Test spoilage rate
Not reported
Concordance rate
Not reported</td></tr>
<tr><td>Yang[9]

China

Case series

DOI:
http://doi.org.10.1101/2020.02.11.20021493</td><td>Population setting:
213 hospitalised with laboratory confirmed COVID-19, 866 samples.

Demographics:
Median age (range): 52 (2-86)
Gender: Male 108 (50.7%)

Clinical characteristics:
Mild: 176
Severe: 37</td><td>Sample site(s):
Nasal swabs (490), throat swabs (205), sputum (142), BALF (29), collected 0-7, 8-14 and ≥15 days after illness onset.

Median number of specimens collected from each patient: 3 (range 1-23).

Test:
quantitative reverse transcription polymerase chain reaction (qRT-PCR) kit: GeneoDX Co

Thresholds:
≤37.0 positive

Gene Targets:
Not reported</td><td>SARS-CoV-2 detection rate
Day 0-7
<table><tr><th>Site</th><th>Mild</th><th>Severe</th></tr><tr><td>Throat</td><td>46/75 (61.3%)</td><td>12/20 (60%)</td></tr><tr><td>Nasal</td><td>147/204 (72.1%)</td><td>11/15 (73.3%)</td></tr><tr><td>Sputum</td><td>37/45 (82.2%)</td><td>8/9 (88.9%)</td></tr><tr><td>BALF</td><td>0</td><td>0</td></tr></table>Day 8-14<table><tr><th>Site</th><th>Mild</th><th>Severe</th></tr><tr><td>Throat</td><td>8/27 (29.6%)</td><td>18/36 (50%)</td></tr><tr><td>Nasal</td><td>96/179 (53.6%)</td><td>34/47 (72.3%)</td></tr><tr><td>Sputum</td><td>32/43 (74.4%)</td><td>15/18 (83.3%)</td></tr><tr><td>BALF</td><td>0</td><td>12/12 (100%)</td></tr></table>Day ≥15<table><tr><th>Site</th><th>Mild</th><th>Severe</th></tr><tr><td>Throat</td><td>1/9 (11.1%)</td><td>14/38 (36.8%)</td></tr><tr><td>Nasal</td><td>6/11 (54.5%)</td><td>17/34 (50%)</td></tr><tr><td>Sputum</td><td>3/7 (42.9%)</td><td>11/18 (61.1%)</td></tr><tr><td>BALF</td><td>0</td><td>11/14 (78.6%)</td></tr></table>Adequate/sufficient sample
Not reported
Test spoilage rate
Not reported
Concordance rate
Not reported</td></tr>
</table>

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Ye, F[29] **China (Luzhou)** **Family cluster** **DOI:** https://doi.org/10.1016/j.ijid.2020.03.042	**Population setting:** 5, familial cluster of patients with laboratory confirmed COVID-19. **Demographics:** *Age range:* 23 to 51 *Gender:* female 2, male 3 **Clinical characteristics:** *Presentation:* First case: fever, dizziness, cough and shortness of breath. Three family members tested positive for COVID-19 presymptomatically while one tested positive the same day as onset of symptoms.	**Sample site(s):** Nasopharyngeal and oropharyngeal swabs and stool and urine samples **Test:** real-time reverse transcription-polymerase chain reaction (RT-PCR) **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Nasopharyngeal: 5 (100%) Oropharyngeal: 5 (100%) Serum: 0 (0%) Stool: 0 (0%) Urine: 0 (0%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported
Ye, G[26] **China (Wuhan)** **Cohort study** **DOI:** 10.1016/j.jhin.2020.03.012	**Population setting:** 91 patients with suspected COVID-19 from 2 hospitals. Hospital 1: 46 Hospital 2: 45 **Demographics:** *Median age:* Not reported *Gender:* Not reported **Clinical characteristics:** *Presentation:* Not reported	**Sample site(s):** Throat swabs, lingual swabs **Test:** real-time reverse transcription-polymerase chain reaction (RT-PCR) **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Throat swabs: 40/91 (44.0%) Lingual swabs: 33/91 (36.3%) *Hospital 1 (1 experienced nurse)* Positive: 25/46 (54.3%) Throat swabs: 25/46 (54.3%) Lingual swabs: 17/46 (36.9%) *Hospital 2 (several nurses)* Positive: 22/45 (48.9%) Throat swabs: 15/45 (33.3%) Lingual swabs: 16/45 (35.6%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** *Hospital 1* All patients with positive lingual swabs also had positive throat swabs. *Hospital 2 (several nurses).* 10/22 (45.5%) of the positive patients were detected by both methods.

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Young[2] **Singapore** **Case series** https://doi.org/10.1001/jama.2020.3204	**Population setting:** 18 laboratory confirmed COVID-19 (PCR, Nasopharyngeal) hospitalised patients. **Demographics:** *Age:* median 47 years (range, 31-73) *Sex:* Male 9 (50%); female 9 (50%) **Clinical characteristics:** *Presentation*: Fever 13 (72%); cough 15 (83%); sore throat 11 (61%); diarrhoea 3 (17%); SOB 2 (11%); Rhinorrhea 1 (6%).	**Sample site(s):** Nasopharyngeal swabs, stool, urine, blood collected at multiple time points in the first 2 weeks **Test:** RT-PCR **Thresholds:** Ct > 38 = negative **Gene Targets:** N, S, and Orf1b	**SARS-CoV-2 detection rate** Stool: 4/8 patients (50%) over 1 to 7 days Whole blood: 1/12 (8%) Urine: 0/10 (0%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported
Zhang, J[17] **China (Jinhua)** **DOI:** /10.1002/jmv.25742	**Population setting:** 14 laboratory-confirmed COVID-19 infections admitted to hospitals (oropharyngeal, RT-PCR assay, all swabs collected by a senior infectious physician with ≥10 years of experience). **Demographics:** *Median age (range):* 41 years (18–87 years) *Gender:* Female 7 (50%) **Clinical characteristics:** *Presentation:* fever (92.8%) and cough (71.4%)	**Sample site(s):** Stool sample **Test:** Not reported **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Stool sample: 5/14 (35.7%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Not reported **Other findings of relevance:** Patients with positive stool samples were also positive for oropharyngeal swabs specimens at least the day before. The trend is that patients with negative stool samples are also negative for oropharyngeal swabs for at least the first 2 days.

Author Country Study design	Population setting Patient demographics Clinical characteristics	Test parameters	Primary outcome results
Zhang, W[18] **China (Wuhan)** **Case Series** **DOI:** http://dx.doi.org/10.1080/22221751.2020.1729071	**Population setting:** 178 laboratory confirmed COVID-19 infections admitted to hospital, but data on 15 patients reported. **Demographics:** Not reported **Clinical characteristics:** Not reported	**Sample site(s):** Oral swabs, anal swabs and blood samples **Test:** qRT-PCR **Thresholds:** Not reported **Gene Targets:** Not reported	**SARS-CoV-2 detection rate** Following some days of treatments (n=15) Oral swabs: 8 (53.3%) Anal swabs: 4 (26.7%) Blood positives: 6 (40%) Serum positives: 3 (20%) **Adequate/sufficient sample** Not reported **Test spoilage rate** Not reported **Concordance rate** Two patients had both positive oral swab and anal swab, none of the blood positives had swabs positive. All serum positives were also blood positive.

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie