

Diagnostic Accuracy of the RapidFor™ RSV/ADV Rapid Test Kit Compared with PCR for the Detection of Respiratory Syncytial Virus and Adenovirus in Nasopharyngeal Swab Samples

Belen Ates

belenterleme@gmail.com

Prof. Dr. Cemil Tascioglu City Hospital, University of Health Sciences

Alper Kacar

Prof. Dr. Cemil Tascioglu City Hospital, University of Health Sciences

Sevilay Kok

Prof. Dr. Cemil Tascioglu City Hospital, University of Health Sciences

Meryem Cansu Olt

Prof. Dr. Cemil Tascioglu City Hospital, University of Health Sciences

Ilhan Gursay

Prof. Dr. Cemil Tascioglu City Hospital, University of Health Sciences

Cigdem Arabaci

Prof. Dr. Cemil Tascioglu City Hospital, University of Health Sciences

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Abstract

Background:

Respiratory syncytial virus (RSV) and adenovirus are important causes of acute respiratory tract infections in children, but their clinical presentations often overlap with those of other viral and bacterial pathogens. Although the polymerase chain reaction (PCR) is the reference standard for diagnosis, rapid antigen tests may provide clinically useful results in emergency settings. This study evaluated the diagnostic accuracy of the RapidFor™ RSV/ADV Rapid Test Kit compared with multiplex PCR in pediatric patients with acute respiratory symptoms.

Methods:

This prospective diagnostic accuracy study included 302 children aged ≤ 18 years who presented to a pediatric emergency department with acute respiratory symptoms from February to May 2025. Two nasopharyngeal swabs were obtained from each participant. The RapidFor™ RSV/ADV Rapid Test Kit was performed immediately at the point of care, and multiplex real-time PCR served as the reference standard. Sensitivity, specificity, positive and negative predictive values, and Cohen's kappa agreement were calculated. Diagnostic performance was also assessed by age group, and multivariable logistic regression was used to identify independent predictors of PCR-confirmed positivity for adenovirus and RSV.

Results:

Adenovirus PCR positivity was detected in 59 patients (19.5%), while RSV PCR positivity was detected in 58 patients (19.2%). The adenovirus rapid test showed a sensitivity of 98.31%, a specificity of 98.77%, a positive predictive value of 95.08%, and a negative predictive value of 99.58%. The RSV rapid test demonstrated similar performance, with a sensitivity of 98.28%, a specificity of 98.77%, a positive predictive value of 95.00%, and a negative predictive value of 99.59%. Agreement with PCR was excellent for both pathogens ($\kappa = 0.958$). RSV positivity was highest among infants younger than one year, whereas adenovirus positivity peaked in school-aged children. Conjunctival injection and fever were independent predictors of adenovirus positivity, while cough and age under one year independently predicted RSV positivity.

Conclusions:

The RapidFor™ RSV/ADV Rapid Test Kit demonstrated high diagnostic accuracy and excellent agreement with multiplex PCR for detecting adenovirus and RSV in children presenting to the emergency department. Its rapid turnaround and ability to detect both pathogens from a single sample may support timely clinical decision-making in pediatric acute care settings.

Background

Adenovirus and respiratory syncytial virus (RSV) are among the most common causes of acute respiratory tract infections in children and are responsible for a significant portion of pediatric emergency visits and hospitalizations worldwide [1, 2]. Globally, over 33 million episodes of RSV-related lower respiratory tract infections occur annually in children under five years old, with approximately 3.6 million of these cases resulting in hospitalization and 118,200 deaths [2]. RSV is the leading cause of lower respiratory tract infections in infants and young children under the age of 2, and it is known that nearly all children experience at least one RSV infection by the age of 2 [3, 4]. Adenovirus, on the other hand, shows a broader age distribution and can cause a wide range of clinical conditions, including pharyngitis, conjunctivitis, bronchiolitis, and pneumonia [5, 6]. Adenovirus is responsible for 5–10% of acute respiratory tract infections in children and is an important pathogen in terms of morbidity and mortality among pediatric cases of pneumonia [7]. The clinical presentations of adenovirus and RSV significantly overlap with those of other respiratory pathogens such as influenza, rhinovirus, and parainfluenza virus; all these agents can cause both upper and lower respiratory tract infections, and clinicians often cannot distinguish the causative agents without laboratory diagnosis [8].

Rapid and accurate pathogen detection has a direct and decisive impact on clinical decision-making, infection control, and antibiotic management. Unnecessary antibiotic prescribing in pediatric emergency departments remains a significant problem, stemming from the inability to reliably determine the etiological diagnosis based on clinical signs in febrile children presenting with respiratory symptoms [9]. Early identification of specific viral pathogens is clinically important for preventing inappropriate antibiotic use, initiating timely antiviral treatment when indicated, and guiding cohorting decisions for hospitalized patients [10]. Currently, the reference standard for detecting viral respiratory pathogens is polymerase chain reaction (PCR) and multiplex PCR platforms, which stand out with their superior analytical sensitivity and specificity [11]. However, the integration of these tests into routine clinical practice is limited by structural constraints, including long turnaround times, the need for centralized laboratory infrastructure, and high unit costs—especially in resource-limited settings such as emergency departments [12].

RADTs provide results within 15–30 minutes, do not require special equipment, and can be performed at the bedside [13]. It has been reported that RSV RADTs demonstrate acceptable sensitivity and specificity, particularly in infants, and these tests have been incorporated into clinical algorithms at many centers [14, 15]. Rapid antigen tests for adenovirus are a recent development, and current data are largely limited to adult cohorts or single-pathogen platforms [16, 17]. Combined platforms that can simultaneously detect adenovirus and RSV from a single nasopharyngeal sample are promising; however, systematic evaluation of the diagnostic accuracy of these tests relative to PCR across the full pediatric age spectrum, from newborns to adolescents, remains limited.

Age-related variability in diagnostic performance is a particularly important issue from a clinical perspective. Viral load, immune response, and sample quality differ significantly across pediatric age groups; sensitivity estimates from adult or mixed-age cohorts cannot be generalized to specific pediatric subgroups [18, 19]. Additionally, the epidemiological distribution of adenovirus and RSV positivity by age

also varies markedly: RSV disproportionately affects infants, while adenovirus positivity is detected at higher rates in older children; this situation can also independently influence test performance metrics [20].

In this study, the diagnostic accuracy of a rapid antigen test for the detection of combined adenovirus and RSV during pediatric emergency department visits was evaluated by comparing it with the reference standard of multiplex PCR. The sensitivity, specificity, positive predictive value, negative predictive value, and agreement with PCR of the test were analyzed separately across five pediatric age groups. As a secondary aim, independent clinical and demographic predictors of adenovirus and RSV infections confirmed by PCR were identified using logistic regression analysis.

Methods

Study design and setting

This prospective diagnostic accuracy study was conducted in the Department of Pediatrics at Prof. Dr. Cemil Taşcıoğlu City Hospital, University of Health Sciences, Turkey, Istanbul. The study was designed and reported in accordance with the STARD 2015 guidelines for diagnostic accuracy studies. Ethical approval was obtained from the Institutional Ethics Committee of Prof. Dr. Cemil Taşcıoğlu City Hospital (Ethics Committee Number: 21; Date: 04/14/2025) and the Turkish Medicines and Medical Devices Agency (E-24931227-511.06.01.02-5838213). Written informed consent was obtained from all parents or legal guardians prior to enrollment, with age-appropriate assent obtained from children where applicable.

Study period and participants

The study was conducted between February and May, 2025. Consecutive eligible pediatric patients presenting to the pediatric emergency department during the study period were invited to participate in order to minimize selection bias. Inclusion criteria were as follows: (1) age ≤ 18 years; (2) presentation with acute respiratory symptoms, including at least one of the following: fever, cough, rhinorrhea, nasal congestion, or wheezing; and (3) parental or guardian consent. Exclusion criteria were: (1) age > 18 years; (2) current or recent antibiotic or antiviral use within 7 days of enrollment; (3) known immunodeficiency or immunosuppressive therapy; (4) inability or refusal to provide informed consent; or (5) incomplete sampling or test data.

Sample size

Sample size estimation followed Buderer's method for diagnostic accuracy studies. Assuming a projected prevalence of adenovirus and RSV positivity of approximately 20%, a target sensitivity of 95%, specificity of 95%, and a precision of $\pm 5\%$ for the 95% confidence interval (CI), the minimum required sample size was calculated as 200 individuals. To account for potential data loss or sampling failures,

planned enrollment was approximately 330 patients. The final cohort consisted of 302 patients, which yielded 95% confidence intervals with satisfactory precision for both sensitivity and specificity estimates.

Specimen collection and testing procedures

After informed consent, two nasopharyngeal swabs were collected from each patient by trained personnel using a standardized technique. The first swab was used immediately to perform the combined adenovirus and RSV rapid antigen detection test (RapidFor™ RSV/ADV Rapid Test Kit, Istanbul, Turkey), yielding results within 5 minutes at the point of care according to the manufacturer's instructions. The second swab was subsequently placed in viral transport medium for multiplex PCR analysis. The rapid antigen test was performed immediately at the point of care; results were recorded by the principal investigator, with each patient assigned a unique study number. Investigators performing the rapid antigen test were blinded to PCR results, and laboratory personnel conducting PCR analysis were blinded to rapid test outcomes.

Reference standard

Multiplex real-time PCR was used as the reference standard for all diagnostic accuracy estimates. Nasopharyngeal specimens in viral transport medium were processed in the hospital microbiology laboratory using the Allplex™ Respiratory Panel Assay (Seegene, Seoul, South Korea), a multiplex PCR panel that detects adenovirus, RSV, rhinovirus, influenza A/B, SARS-CoV-2, *Streptococcus pyogenes*, and *Streptococcus pneumoniae*. Nucleic acid amplification and real-time detection were performed on a Bio-Rad CFX96/CFX384 Real-Time PCR Detection System (Bio-Rad Laboratories, Hercules, CA, USA). All PCR procedures were performed in accordance with the manufacturer's instructions and the laboratory's standard operating procedures and routine quality-control practices.

Clinical data collection

Demographic characteristics and clinical findings were recorded at presentation, including age, sex, duration of symptoms, and the presence of fever, cough, rhinorrhea, nasal congestion, vomiting, diarrhea, seizure, conjunctival injection, sore throat, headache, and wheezing.

Statistical analysis

All analyses were conducted using IBM SPSS Statistics Version 27.0 (IBM Corp., Armonk, NY, USA). Categorical variables are presented as frequencies and percentages. The diagnostic performance of the combined adenovirus and RSV rapid antigen detection test – including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) – was calculated using standard formulas with multiplex PCR as the reference standard. The Wilson score method was used to compute 95% confidence intervals for overall diagnostic accuracy estimates; age-stratified estimates were presented

descriptively because of small cell counts in some subgroups. Agreement between rapid test and PCR results was assessed using Cohen's kappa coefficient, interpreted according to the Landis and Koch criteria. Age-stratified comparisons of rapid test and PCR positivity rates were evaluated using the Chi-square test. Multivariable logistic regression analysis was performed to identify independent clinical and demographic predictors of PCR-confirmed adenovirus and RSV positivity. Variables were selected based on clinical relevance and univariate screening at $p < 0.20$; the final model retained variables that were statistically significant ($p < 0.05$) and clinically important confounders. Adjusted odds ratios (ORs) with 95% CIs are reported. Multicollinearity was assessed using variance inflation factors (VIF < 5 considered acceptable). The Hosmer–Lemeshow goodness-of-fit test was used to assess model calibration, and model discrimination was evaluated using the area under the receiver operating characteristic curve (AUC). All tests were two-tailed, and a p -value < 0.05 was considered statistically significant.

Results

Table 1
Demographic Characteristics of the Study
Population (n = 302)

Variable	Group	n (%)
Age group	< 1 year	94 (31.1)
	1–3 years	83 (27.5)
	4–6 years	46 (15.2)
	7–12 years	64 (21.2)
	13–18 years	15 (5.0)
Sex	Male	180 (59.8)
	Female	121 (40.2)
Total		302 (100.0)

Values are presented as number and percentage.

A total of 302 pediatric patients were enrolled. The largest age subgroup was infants under 1 year (31.1%), followed by children aged 1–3 years (27.5%). Male patients constituted 59.8% of the cohort.

Clinical Presentation in PCR-Confirmed Cases

Table 2
Symptom Distribution by Age Group Among Adenovirus PCR-Positive Patients (n = 59)

Symptom	< 1 year (n = 2)	1–3 year (n = 13)	4–6 year (n = 13)	7–12 year (n = 29)	13–18 year (n = 2)	p
Fever	2/2 (100.0)	12/13 (92.3)	13/13 (100.0)	20/29 (69.0)	2/2 (100.0)	0.080
Cough	0/2 (0.0)	7/13 (53.8)	4/13 (30.8)	10/29 (34.5)	0/2 (0.0)	0.374
Rhinorrhea	0/2 (0.0)	3/13 (23.1)	1/13 (7.7)	10/29 (34.5)	0/2 (0.0)	0.293
Nasal congestion	0/2 (0.0)	0/13 (0.0)	0/13 (0.0)	1/29 (3.4)	0/2 (0.0)	0.902
Vomiting	1/2 (50.0)	1/13 (7.7)	2/13 (15.4)	0/29 (0.0)	0/2 (0.0)	0.046
Diarrhea	1/2 (50.0)	0/13 (0.0)	1/13 (7.7)	3/29 (10.3)	0/2 (0.0)	0.201
Conjunctival injection	0/2 (0.0)	3/13 (23.1)	3/13 (23.1)	10/29 (34.5)	1/2 (50.0)	0.714
Sore throat	0/2 (0.0)	0/13 (0.0)	2/13 (15.4)	6/29 (20.7)	1/2 (50.0)	0.264
Wheezing	0/2 (0.0)	0/13 (0.0)	0/13 (0.0)	0/29 (0.0)	0/2 (0.0)	—

Values are presented as n/N (%). Fisher's exact test. * Vomiting was the only symptom with a statistically significant age-related variation ($p = 0.046$). — denotes symptoms absent in all age groups.

Table 3
Symptom Distribution by Age Group Among RSV PCR-Positive Patients (n = 58)

Symptom	< 1 year (n = 48)	1–3 year (n = 4)	4–6 year (n = 4)	7–12 year (n = 1)	13–18 year (n = 1)	p
Fever	19/48 (39.6)	2/4 (50.0)	2/4 (50.0)	1/1 (100.0)	1/1 (100.0)	0.552
Cough	46/48 (95.8)	4/4 (100.0)	4/4 (100.0)	0/1 (0.0)	1/1 (100.0)	0.001
Rhinorrhea	14/48 (29.2)	2/4 (50.0)	0/4 (0.0)	0/1 (0.0)	0/1 (0.0)	0.501
Nasal congestion	8/48 (16.7)	0/4 (0.0)	0/4 (0.0)	0/1 (0.0)	0/1 (0.0)	0.748
Vomiting	0/48 (0.0)	0/4 (0.0)	0/4 (0.0)	0/1 (0.0)	0/1 (0.0)	—
Diarrhea	0/48 (0.0)	0/4 (0.0)	0/4 (0.0)	0/1 (0.0)	0/1 (0.0)	—
Conjunctival injection	0/48 (0.0)	0/4 (0.0)	0/4 (0.0)	0/1 (0.0)	0/1 (0.0)	—
Sore throat	0/48 (0.0)	0/4 (0.0)	0/4 (0.0)	0/1 (0.0)	0/1 (0.0)	—
Wheezing	3/48 (6.2)	0/4 (0.0)	1/4 (25.0)	0/1 (0.0)	0/1 (0.0)	0.642

Values are presented as n/N (%). Fisher's exact test. Cough showed a statistically significant age-related variation (p = 0.001). — denotes symptoms absent in all groups. Note: the 7–12-year and 13–17-year groups each contained only one RSV-positive patient; results in these groups should be interpreted with caution.

The clinical profiles of adenovirus and RSV infections differed markedly in both symptom pattern and age distribution. Among adenovirus PCR-positive patients, fever was the dominant symptom across all age groups (69.0–100.0%), while conjunctival injection and sore throat increased progressively with age. Vomiting was most frequent in infants (50.0%) and showed a statistically significant age-related variation (p = 0.046). Among RSV PCR-positive patients, cough was the predominant symptom (95.8% in infants), with statistically significant variation by age across groups (p = 0.001). In our study, RSV-positive patients predominantly presented with respiratory symptoms, whereas gastrointestinal symptoms, conjunctival injection, sore throat, and headache were not observed among RSV-positive cases.

Table 4
Comparison of Symptom Profiles Between Adenovirus and RSV PCR-Positive Patients

Symptom	Adenovirus PCR + n = 59	RSV PCR + n = 58	p
Fever	49/59 (83.1)	25/58 (43.1)	< 0.001
Cough	21/59 (35.6)	55/58 (94.8)	< 0.001
Rhinorrhea	14/59 (23.7)	16/58 (27.6)	0.790
Nasal congestion	1/59 (1.7)	8/58 (13.8)	0.017
Vomiting	4/59 (6.8)	0/58 (0.0)	0.119
Diarrhea	5/59 (8.5)	0/58 (0.0)	0.057
Conjunctival injection	17/59 (28.8)	0/58 (0.0)	< 0.001
Sore throat	9/59 (15.3)	0/58 (0.0)	0.003
Wheezing	0/59 (0.0)	4/58 (6.9)	0.057

Chi-square test or Fisher's exact test as appropriate. Bold values indicate statistical significance ($p < 0.05$).

Direct comparison of symptom profiles between adenovirus and RSV PCR-positive patients revealed highly significant differences in key clinical features (Table 4). Fever was significantly more frequent in adenovirus-positive patients (83.1% vs 43.1%; $p < 0.001$), whereas cough predominated in RSV-positive patients (94.8% vs 35.6%; $p < 0.001$). Conjunctival injection was exclusively observed in adenovirus-positive patients (28.8% vs 0.0%; $p < 0.001$), as was sore throat (15.3% vs 0.0%; $p = 0.003$). Nasal congestion was more frequent in RSV-positive patients (13.8% vs 1.7%; $p = 0.017$). Wheezing tended to be more common in RSV-positive patients (6.9% vs 0.0%; $p = 0.057$), though this difference did not reach statistical significance.

Table 5
Univariate Analysis of Clinical Predictors of Adenovirus PCR Positivity

Variable	Adeno PCR + n=59	Adeno PCR – n=243	OR (95% CI)	p
Fever	49/59 (83.1)	160/243 (65.8)	2.54 (1.22–5.27)	0.016
Cough	21/59 (35.6)	133/243 (54.7)	0.46 (0.25–0.82)	0.013
Rhinorrhea	14/59 (23.7)	51/243 (21.0)	1.17 (0.60–2.30)	0.777
Nasal congestion	1/59 (1.7)	25/243 (10.3)	0.15 (0.02–1.13)	0.037
Vomiting	4/59 (6.8)	19/243 (7.8)	0.86 (0.28–2.62)	1.000
Diarrhea	5/59 (8.5)	14/243 (5.8)	1.51 (0.52–4.39)	0.638
Conjunctival injection	17/59 (28.8)	5/243 (2.1)	19.27 (6.74–55.04)	< 0.001
Sore throat	9/59 (15.3)	21/243 (8.6)	1.90 (0.82–4.40)	0.200
Wheezing	0/59 (0.0)	6/243 (2.5)	—	0.601

OR: odds ratio; CI: confidence interval. Chi-square or Fisher's exact test. Bold values indicate $p < 0.05$. — OR not calculable due to zero cell count.

Table 6
Univariate Analysis of Clinical Predictors of RSV PCR Positivity

Variable	RSV PCR + n=58	RSV PCR – n=244	OR (95% CI)	p
Fever	25/58 (43.1)	184/244 (75.4)	0.25 (0.14–0.45)	< 0.001
Cough	55/58 (94.8)	99/244 (40.6)	26.85 (8.17–88.25)	< 0.001
Rhinorrhea	16/58 (27.6)	49/244 (20.1)	1.52 (0.79–2.92)	0.284
Nasal congestion	8/58 (13.8)	18/244 (7.4)	2.01 (0.83–4.88)	0.192
Vomiting	0/58 (0.0)	23/244 (9.4)	—	0.011
Diarrhea	0/58 (0.0)	19/244 (7.8)	—	0.030
Conjunctival injection	0/58 (0.0)	22/244 (9.0)	—	0.011
Sore throat	0/58 (0.0)	30/244 (12.3)	—	0.002
Wheezing	4/58 (6.9)	2/244 (0.8)	8.96 (1.60–50.20)	0.014

OR: odds ratio; CI: confidence interval. Chi-square or Fisher's exact test. Bold values indicate $p < 0.05$. — OR not calculable due to zero cell count.

Univariate analyses identified several variables significantly associated with adenovirus PCR positivity (Table 5). Conjunctival injection demonstrated the strongest association (OR 19.27, 95% CI 6.74–55.04; $p < 0.001$), followed by fever (OR 2.54, 95% CI 1.22–5.27; $p = 0.016$). Cough was inversely associated with adenovirus positivity (OR 0.46, 95% CI 0.25–0.82; $p = 0.013$), as was nasal congestion (OR 0.15, 95% CI 0.02–1.13; $p = 0.037$). For RSV positivity, cough demonstrated the strongest univariate association (OR 26.85, 95% CI 8.17–88.25; $p < 0.001$), while fever was inversely associated (OR 0.25, 95% CI 0.14–0.45; $p < 0.001$). Wheezing was significantly more frequent in RSV-positive patients (OR 8.96, 95% CI 1.60–50.20; $p = 0.014$). Vomiting, diarrhea, conjunctival injection, and sore throat were each significantly less common in RSV-positive patients (all $p \leq 0.030$).

PCR Positivity by Age and Sex

Table 7
Adenovirus PCR Positivity by Age Group

Age Group	Negative n (%)	Positive n (%)	Total	p
< 1 year	92 (97.9%)	2 (2.1%)	94	
1–3 years	64 (77.1%)	19 (22.9%)	83	
4–6 years	31 (67.4%)	15 (32.6%)	46	
7–12 years	43 (67.2%)	21 (32.8%)	64	
13–18 years	13 (86.7%)	2 (13.3%)	15	
Total	243 (80.5%)	59 (19.5%)	302	0.001

Chi-square test. $p = 0.001$ for overall comparison across age groups.

Table 8
RSV PCR Positivity by Age Group

Age Group	Negative n (%)	Positive n (%)	Total	p
< 1 year	46 (48.9%)	48 (51.1%)	94	
1–3 years	78 (94.0%)	5 (6.0%)	83	
4–6 years	43 (93.5%)	3 (6.5%)	46	
7–12 years	63 (98.4%)	1 (1.6%)	64	
13–18 years	14 (93.3%)	1 (6.7%)	15	
Total	244 (80.8%)	58 (19.2%)	302	0.001

Chi-square test. $p = 0.001$ for overall comparison across age groups.

Adenovirus PCR positivity differed significantly by age group ($p = 0.001$), with the highest positivity rates observed in children aged 7–12 years (32.8%) and 4–6 years (32.6%), whereas infants younger than 1 year had the lowest positivity rate (2.1%). RSV positivity was highest in infants (51.1%) and declined sharply with increasing age (6.0% at 1–3 years; 1.6% at 7–12 years; $p = 0.001$).

Table 9
PCR Positivity by Sex

Sex	Adenovirus Positive n (%)	Adenovirus Negative n (%)	RSV Positive n (%)	RSV Negative n (%)
Male	33 (18.3%)	147 (81.7%)	33 (18.3%)	147 (81.7%)
Female	26 (21.5%)	95 (78.5%)	25 (20.7%)	96 (79.3%)
Total	59 (19.5%)	242 (80.5%)	58 (19.2%)	243 (80.8%)
p	0.469		0.796	

Chi-square test.

Neither adenovirus nor RSV positivity differed significantly by sex (adenovirus: $p = 0.469$; RSV: $p = 0.796$).

Diagnostic Performance of the Rapid Antigen Tests

Table 10
Comparative Performance of the Adenovirus
Rapid Test Against PCR

Metric	Estimate, %	95% CI
Sensitivity	98.31	91.00–99.70
Specificity	98.77	96.43–99.58
PPV	95.08	86.51–98.31
NPV	99.58	97.69–99.93
Cohen’s κ	0.958	—

CI: confidence interval; PPV: positive predictive value; NPV: negative predictive value. Confidence intervals were calculated using the Wilson score method.

Table 11
Comparative Performance of the RSV Rapid
Test Against PCR

Metric	Estimate, %	95% CI
Sensitivity	98.28	90.86–99.69
Specificity	98.77	96.45–99.58
PPV	95.00	86.30–98.29
NPV	99.59	97.70–99.93
Cohen's κ	0.958	—

CI: confidence interval; PPV: positive predictive value; NPV: negative predictive value. Confidence intervals were calculated using the Wilson score method.

The adenovirus rapid test achieved sensitivity of 98.31%, specificity of 98.77%, PPV of 95.08%, and NPV of 99.58% (Table 10). The RSV rapid test demonstrated comparable accuracy: sensitivity 98.28%, specificity 98.77%, PPV 95.00%, and NPV 99.59% (Table 11). Agreement with PCR was excellent for both pathogens ($\kappa = 0.958$; $p < 0.001$ for both).

Age-Stratified Diagnostic Performance

Table 12
Age-Stratified Diagnostic Performance of the Adenovirus Rapid Test

Age Group	n	Sensitivity (%)	Specificity (%)	PPV (%)	κ
< 1 year	94	100.0	98.9	66.7	0.795
1–3 years	83	100.0	100.0	100.0	1.000
4–6 years	46	100.0	100.0	100.0	1.000
7–12 years	64	95.2	95.3	90.9	0.918
13–18 years	15	100.0	100.0	100.0	1.000
Overall	302	98.31	98.77	95.08	0.958

Values are presented as percentages. Age-stratified diagnostic performance estimates are shown descriptively without confidence intervals because of small cell counts in some subgroups. PPV: positive predictive value; κ : Cohen's kappa.

Table 13
Age-Stratified Diagnostic Performance of the RSV Rapid Test

Age Group	n	Sensitivity (%)	Specificity (%)	PPV (%)	κ
< 1 year	94	97.9	97.8	97.9	0.957
1–3 years	83	100.0	97.4	71.4	0.784
4–6 years	46	100.0	100.0	100.0	1.000
7–12 years	64	100.0	100.0	100.0	1.000
13–18 years	15	100.0	100.0	100.0	1.000
Overall	302	98.28	98.77	95.00	0.958

Values are presented as percentages. Age-stratified diagnostic performance estimates are shown descriptively without confidence intervals because of small cell counts in some subgroups. PPV: positive predictive value; κ : Cohen's kappa.

The adenovirus rapid test achieved 100% sensitivity and specificity in the 1–3, 4–6, and 13–18 year groups ($\kappa = 1.000$). In infants, sensitivity was 100% with one false positive (specificity 98.9%; $\kappa = 0.795$). The 7–12 year group showed marginally lower performance (sensitivity 95.2%, specificity 95.3%; $\kappa = 0.918$). The RSV rapid test achieved 100% sensitivity and specificity in the 4–6, 7–12, and 13–18 year groups ($\kappa = 1.000$). In infants, one false positive and one false negative reduced sensitivity to 97.9% and specificity to 97.8% ($\kappa = 0.957$). In the 1–3-year group, two false-positive results yielded a specificity of 97.4% and a PPV of 71.4% ($\kappa = 0.784$). Because of the small number of PCR-positive cases in some age strata, age-stratified diagnostic performance estimates were presented descriptively without confidence intervals.

Predictors of PCR Positivity: Multivariable Logistic Regression

Table 14
Multivariable Logistic Regression Analysis of Predictors of Adenovirus
PCR Positivity

Variable	β	OR	95% CI	p
Fever	1.075	2.93	1.14–7.69	0.027
Conjunctival injection	2.729	15.32	4.55–50.00	< 0.001
Age < 1 year	1.971	7.178	1.58–32.68	0.011
Age 3–6 years	-0.768	0.464	0.197–1.09	0.078
Age 7–12 years	-0.401	0.67	0.298–1.506	0.332
Symptom duration	0.146	1.158	0.949–1.412	0.148
Cough	0.040	1.041	0.516–2.096	0.912
Nasal congestion	1.251	3.493	0.388–31.453	0.265

OR: odds ratio; CI: confidence interval. Model: $\chi^2 = 74.39$, $p < 0.001$; Nagelkerke $R^2 = 0.348$; Hosmer–Lemeshow: $\chi^2 = 5.358$, $df = 8$, $p = 0.719$; AUC = 0.833 (95% CI 0.780–0.886). Bold: $p < 0.05$.

The multivariable model for adenovirus positivity was statistically significant ($\chi^2 = 74.39$; $p < 0.001$; Nagelkerke $R^2 = 0.348$; Hosmer–Lemeshow $p = 0.719$). Conjunctival injection was the strongest independent predictor (OR 15.32, 95% CI 4.545–52.632; $p < 0.001$), followed by age under 1 year (OR 7.178, 95% CI 1.576–32.682; $p = 0.011$) and fever (OR 2.93, 95% CI 1.131–7.575; $p = 0.027$). The ROC curve yielded an AUC of 0.833 (95% CI 0.780–0.886; $p < 0.001$), indicating good discriminatory ability (Fig. 1).

The model demonstrated good discriminatory performance (AUC = 0.833, 95% CI: 0.780–0.886, $p < 0.001$). AUC: area under the curve; CI: confidence interval; PCR: polymerase chain reaction.

Table 15
Multivariable Logistic Regression Analysis of Predictors of RSV PCR
Positivity

Variable	β	OR	95% CI	p
Cough	3.271	26.342	6.802–102.04	< 0.001
Age < 1 year	2.582	13.223	1.522–114.94	0.019
Wheezing	2.410	11.134	0.867–142.85	0.064
Fever	0.479	1.614	0.703–3.709	0.259
Symptom duration	-0.150	0.861	0.659–1.125	0.272

OR: odds ratio; CI: confidence interval. Bold: $p < 0.05$. Model: $\chi^2 = 140.86$, $p < 0.001$; Nagelkerke $R^2 = 0.597$; Hosmer–Lemeshow: $\chi^2 = 9.586$, $df = 8$, $p = 0.295$; AUC = 0.925 (95% CI 0.886–0.963).

The RSV model demonstrated high explanatory power ($\chi^2 = 140.86$; $p < 0.001$; Nagelkerke $R^2 = 0.597$; Hosmer–Lemeshow $p = 0.295$). Cough was the dominant predictor (OR 26.342, 95% CI 6.802–102.04; $p < 0.001$). Age under 1 year conferred 13.2-fold increased odds (OR 13.223, 95% CI 1.522–114.94; $p = 0.019$). Wheezing showed a trend toward significance (OR 11.134; $p = 0.064$). The AUC was 0.925 (95% CI 0.886–0.963; $p < 0.001$), reflecting excellent discriminatory performance (Fig. 2).

The model demonstrated excellent discriminatory performance (AUC = 0.925, 95% CI: 0.886–0.963, $p < 0.001$). AUC: area under the curve; CI: confidence interval; PCR: polymerase chain reaction; RSV: respiratory syncytial virus.

Discussion

In this prospective pediatric emergency department cohort, the RapidFor™ RSV/ADV Rapid Test Kit showed excellent agreement with multiplex PCR for both respiratory syncytial virus (RSV) and adenovirus. The main contribution of this study is that a combined point-of-care antigen platform was evaluated in a real-world pediatric setting across predefined age groups. Overall sensitivity, specificity, and negative predictive values were high for both pathogens, suggesting that the test may be useful as a rapid rule-out tool when timely PCR is not readily available. Nevertheless, the age-stratified estimates should be interpreted as exploratory because several subgroups included few PCR-positive cases.

Interpretation of diagnostic performance

The RSV component performed better than the pooled sensitivity reported in earlier meta-analyses of RSV rapid antigen tests, while maintaining similarly high specificity [14, 15]. This difference may reflect improvements in assay design, standardized nasopharyngeal sampling, and the predominance of infants and young children in the RSV-positive group, in whom higher viral loads can improve antigen test performance [21, 22]. For adenovirus, previous pediatric emergency department studies reported more modest sensitivity for immunochromatographic or fluorescence immunoassay platforms [16, 23]. The higher accuracy observed in the present study is encouraging, but direct comparison should be cautious because diagnostic performance is influenced by assay technology, specimen type, symptom duration, circulating strains, and the reference PCR method.

Age distribution and clinical interpretation

The epidemiological patterns observed in this cohort were clinically plausible. RSV positivity was concentrated in infants, consistent with the high burden of RSV lower respiratory tract infection in the first years of life [1, 2]. Adenovirus positivity was more frequent among preschool and school-aged children, in line with its broader clinical and age distribution [5–7]. Because predictive values depend strongly on disease prevalence, the lower positive predictive values seen in low-prevalence age strata

should not be interpreted as poor analytical performance alone. These findings emphasize that rapid antigen results should be interpreted together with patient age, season, local circulation patterns, and pre-test probability, particularly in the post-pandemic period when RSV seasonality and age distribution have shown atypical patterns [24, 25].

The clinical findings also supported the biological differences between the two pathogens. Fever and conjunctival injection were more suggestive of adenovirus, consistent with the known ocular and pharyngoconjunctival tropism of adenovirus [6, 26, 27]. In contrast, cough and age under 1 year were the strongest independent predictors of RSV positivity, which is consistent with RSV's predominance as a lower respiratory tract pathogen in infants [3]. However, symptoms alone cannot reliably distinguish viral etiologies in emergency practice. The regression models should therefore be viewed as a supportive clinical context rather than substitutes for laboratory confirmation, especially because some estimates had wide confidence intervals due to sparse events.

Clinical implications

A combined RSV/adenovirus point-of-care assay may have practical value in pediatric acute care by shortening time to etiologic information, supporting cohorting decisions, and reducing diagnostic uncertainty. This is particularly relevant because unnecessary antibiotic prescribing remains common in children with respiratory symptoms [9]. Previous studies suggest that rapid viral testing can support antimicrobial stewardship, although its effect on antibiotic prescribing is variable and depends on integration into clinical pathways rather than test availability alone [28–31]. The ability to detect both RSV and adenovirus from a single nasopharyngeal specimen within minutes may therefore be most useful when embedded in local protocols that combine rapid testing with clear criteria for antibiotic use, isolation, discharge, and follow-up. Recent pediatric emergency department data also suggest that rapid adenovirus antigen testing can reduce observation time and hospitalization in selected patients [32].

Limitations

This study has limitations. It was conducted at a single center over a limited February–May study period; therefore, the findings may not fully represent different geographic settings or the full seasonal distribution of RSV and adenovirus. Although the overall sample size was adequate for primary diagnostic accuracy estimates, several age-specific subgroups, particularly older children with RSV and infants with adenovirus, included few positive cases. For this reason, age-stratified performance measures were reported descriptively and should be validated in larger multicenter cohorts. In addition, clinical symptoms were recorded at the time of emergency department presentation, and changes in symptom evolution before or after sampling could not be fully captured. Finally, the study evaluated one commercial platform against multiplex PCR, so the findings should not be generalized to other rapid antigen assays without direct validation.

Conclusions

The RapidFor™ RSV/ADV Rapid Test Kit demonstrated high sensitivity and specificity for both adenovirus and RSV detection compared with multiplex PCR in a pediatric emergency department cohort, with excellent overall agreement ($\kappa = 0.958$) across all age groups. RSV positivity was concentrated among infants, whereas adenovirus positivity peaked among school-age children. Conjunctival injection and fever were independent predictors of adenovirus PCR positivity, whereas cough and age under one year were the strongest predictors of RSV positivity. The combined platform allows simultaneous detection of both pathogens from a single nasopharyngeal specimen within minutes, which may support clinical decision-making in resource-limited settings. Multicenter studies with broader seasonal coverage are needed to confirm these findings.

Abbreviations

ADV

Adenovirus

AUC

Area under the receiver operating characteristic curve

CI

Confidence interval

ED

Emergency department

NPV

Negative predictive value

OR

Odds ratio

PCR

Polymerase chain reaction

PPV

Positive predictive value

RADT

Rapid antigen detection test

ROC

Receiver operating characteristic

RSV

Respiratory syncytial virus

SARS-CoV-2

Severe acute respiratory syndrome coronavirus 2

STARD

Standards for Reporting of Diagnostic Accuracy Studies

VIF

Variance inflation factor.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee of Prof. Dr. Cemil Taşcıoğlu City Hospital, University of Health Sciences, Istanbul, Türkiye (approval number: 21; date: 14 April 2025), and the study was additionally authorised by the Turkish Medicines and Medical Devices Agency (TİTCK; reference number E-24931227-511.06.01.02-5838213). Written informed consent was obtained from all parents or legal guardians prior to enrolment, with age-appropriate assent obtained from children where applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available in order to protect participant privacy but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Conceptualization, Belen Ates, Alper Kacar, Sevilay Kok, Ilhan Gursoy, Meryem Cansu Olt and Cigdem Arabaci; methodology, Belen Ates and Cigdem Arabaci; validation, Belen Ates and Cigdem Arabaci; formal analysis, Belen Ates and Meryem Cansu Olt; investigation, Belen Ates, Meryem Cansu Olt, Alper Kacar, Sevilay Kok, Ilhan Gursoy, and Cigdem Arabaci; resources, Alper Kacar and Ilhan Gursoy; data curation, Meryem Cansu Olt, Alper Kacar, and Sevilay Kok; writing—original draft preparation, Belen Ates; writing—review and editing, all authors; supervision, Belen Ates; project administration, Belen Ates. All authors have read and agreed to the published version of the manuscript.

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Figures

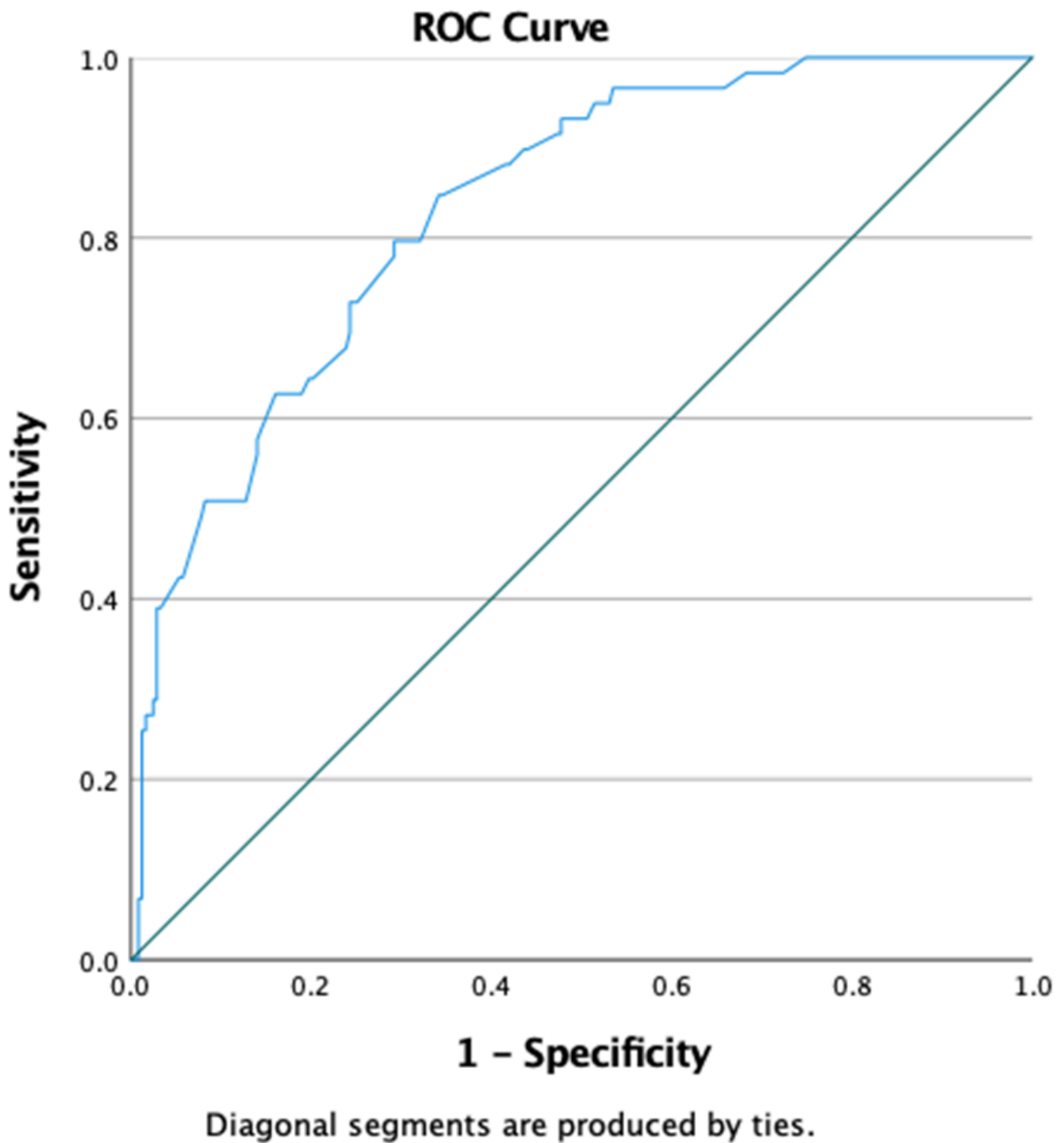


Figure 1

Receiver operating characteristic (ROC) curve for the multivariable logistic regression model predicting adenovirus PCR positivity.

The model demonstrated good discriminatory performance (AUC = 0.833, 95% CI: 0.780–0.886, $p < 0.001$). AUC: area under the curve; CI: confidence interval; PCR: polymerase chain reaction.

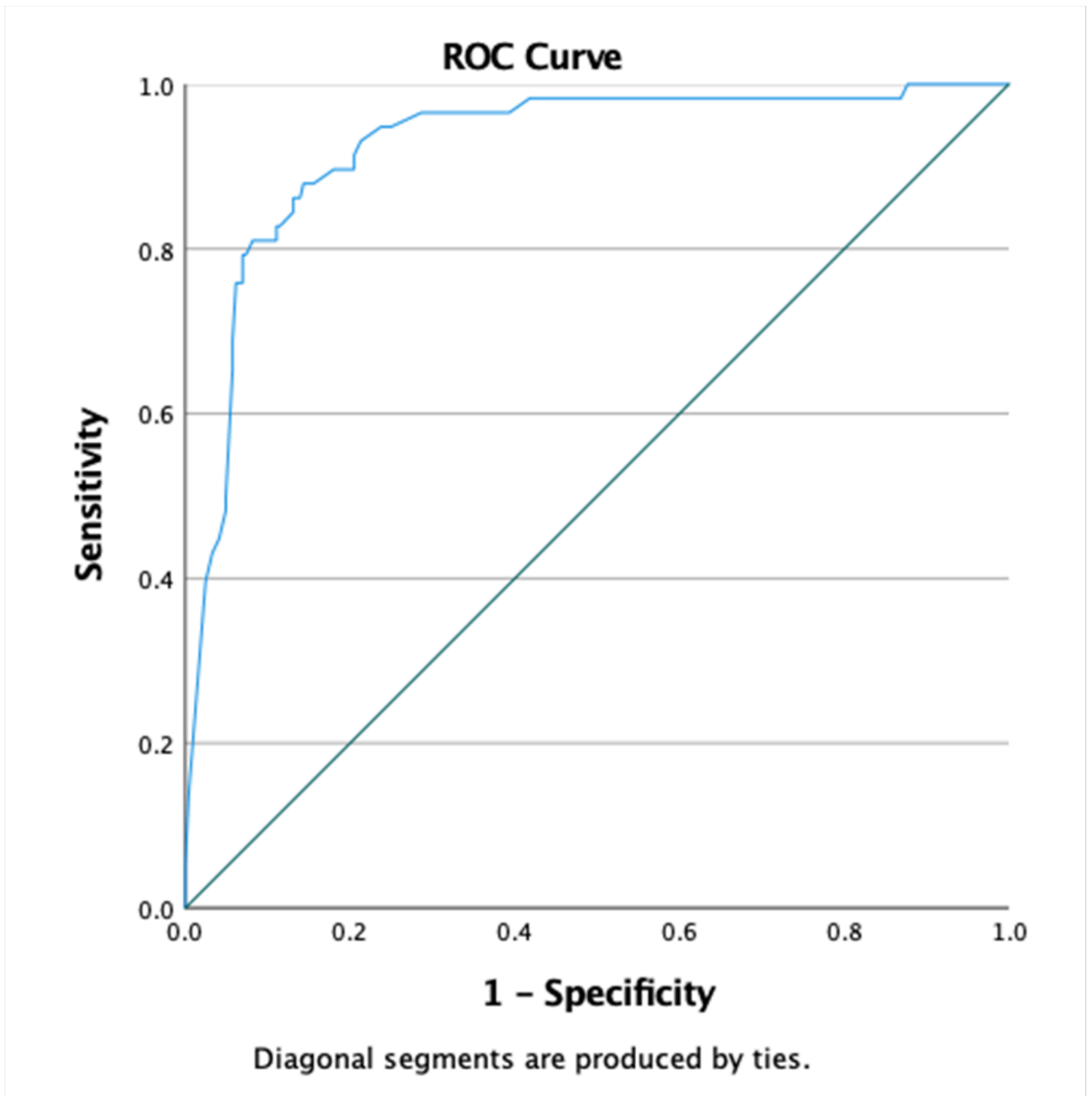


Figure 2

Receiver operating characteristic (ROC) curve for the multivariable logistic regression model predicting RSV PCR positivity.

The model demonstrated excellent discriminatory performance (AUC = 0.925, 95% CI: 0.886–0.963, $p < 0.001$). AUC: area under the curve; CI: confidence interval; PCR: polymerase chain reaction; RSV: respiratory syncytial virus.