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RESEARCH ARTICLE

DISCRIMINATING CAPACITY OF SERUM A1-ANTITRYPSIN IN NIGERIAN TB CARE

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ABSTRACT

α1-antitrypsin (A1AT) levels in active TB is not consistent and performance in routine Nigerian care is not well defined . A cross-sectional, three-arm case–control study with N = 75 (25 Non-TB; 25 NewDx; 25 Treated TB) was conducted. Serum A1AT measured by immunoassay. We compared groups via ANOVA and Welch post-hoc with Hedges g; and estimated ROC AUCs with bootstrap 95% CIs. A1AT was highest in NewDx TB (293.7 ± 73.9 mg/dL) vs Non-TB (151.5 ± 25.9) and Treated TB (160.0 ± 22.6); ANOVA $p < 0.001$. Discrimination for Non-TB vs NewDx: AUC 0.928 (95% CI 0.833–1.000), threshold ~220 mg/dL, sensitivity 0.88, specificity 1.00; for Non-TB vs All-TB: AUC 0.772 (0.667–0.869), threshold ~167 mg/dL, sensitivity 0.68, specificity 0.80. In Nigerian care, A1AT provides excellent triage discrimination for newly diagnosed TB and moderate discrimination when treated cases are included. A1AT-guided referral to confirmatory testing warrants multi-site validation, quality assurance, and cost-effectiveness evaluation.

KEYWORDS

Alpha-1 antitrypsin, Pulmonary tuberculosis, Diagnostic triage, Biomarker, Nigeria

1. INTRODUCTION

Tuberculosis (TB) persists as a leading cause of death from an infectious agent worldwide. In 2023, incidence levels returned to near-record highs, resulting in approximately 1.25 million deaths, despite longstanding global control initiatives (World Health Organization [WHO], 2024). Nigeria, among the 30 high-burden countries, continues to face significant diagnostic and care-cascade gaps that hinder progress toward End TB targets, even with recent improvements in case notification (Oga-Omenka et al., 2020; National Tuberculosis, Leprosy and Buruli Ulcer Control Programme [NTBLCP], 2025).

This context underscores a critical need for non-sputum triage tools suitable for peripheral healthcare settings. The WHO target product profile (TPP) for triage tests prioritizes high sensitivity (≥90%) with at least moderate specificity (≥70%), a benchmark that remains challenging for point-of-care devices according to recent evidence (Richardson et al., 2023; de Nooy et al., 2025; Kohli et al., 2025). C-reactive protein (CRP) is the most widely used host-response biomarker for this purpose (WHO, 2024; Derendinger et al., 2024). However, at the recommended threshold of ≥5 mg/L, its accuracy generally falls short of TPP goals, with pooled sensitivity around 84% and specificity near 61% (Derendinger et al., 2024).

Serum α1-antitrypsin (A1AT), a hepatically synthesized serine protease inhibitor (serpin) and positive acute-phase reactant, represents a biologically plausible TB biomarker(de Melo et al., 2019. Its levels are elevated in active pulmonary TB compared to controls, as demonstrated in multiple proteomic and case-control studies, including one conducted in northern Nigeria (Song et al., 2014; Li et al., 2022). Conversely, mechanistic studies in severe disease have observed relative depletion of circulating A1AT due to neutrophil extracellular trap (NET) activity, indicating disease-stage heterogeneity (de Melo et al., 2019). The diagnostic and therapeutic potential of A1AT in infectious diseases, including TB, continues to be an area of investigation (Indalao et al., 2019). Despite this, the performance of A1AT as a standalone triage test, particularly in relation to current TPP standards and CRP, is not well-established and findings are inconsistent, especially in the Nigerian context (Bystrom,2011; Damburam et al., 2012; Song et al., 2014; Santos et al., 2019).

To address this, we assessed the diagnostic discrimination of serum A1AT across three well-defined groups in a Nigerian cohort: Non-TB, Newly Diagnosed TB (NewDx), and Treated TB. We quantified its accuracy against two programmatically relevant comparisons: Non-TB versus NewDx, and Non-TB versus All-TB (combining NewDx and Treated patients).

2. METHODS

2.1 Study design

We conducted a cross-sectional, three-arm case–control study in routine Nigerian TB care. Participants were enrolled into Non-TB, NewDx, and Treated TB groups; analyses used the complete observed sample (N = 75; 25 per group). The prespecified analytic aim was to estimate the discriminative capacity of A1AT for Non-TB vs NewDx (primary triage use-case) and Non-TB vs All-TB (secondary).

2.2 Study population and selection

Adults (≥18 years) attending outpatient clinics were screened consecutively. Non-TB participants had no clinical/radiographic TB and were not on anti-TB therapy. NewDx TB participants had bacteriologically confirmed pulmonary TB prior to treatment initiation. Treated TB

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participants were on therapy with clinical improvement. Exclusions included overt hepatic failure, acute bacterial coinfection requiring parenteral antibiotics, or inability to consent. Enrollment continued until each group reached n = 25.

2.3 Data collection

Demographic and anthropometric data (age, sex, height, weight) were recorded at enrollment; BMI was computed as weight/height^2. Clinical classification (Non-TB, NewDx, Treated TB) and treatment status were verified from records. The primary biomarker was serum A1AT (mg/dL) measured at enrollment. Study forms were double-entered and cross-checked prior to analysis.

2.4 Sample processing and laboratory analysis

Venous blood was collected into serum tubes and processed per hospital SOPs. Following clot formation and centrifugation, serum was aliquoted and analyzed same-day. A1AT was quantified using a standardized immunoturbidimetry on a Behring Nephelometer II (Dade Behring) as earlier describe (Donato et al., 2015). Results were reported in mg/dL. No freeze–thaw cycles were used for primary measurements.

2.5 Ethical clearance

The protocol adhered to the Declaration of Helsinki and received approval from the ethics committee of Oyo State Ministry of Health (NHREC/OYOSHRIEC/10/11/22). All participants provided written informed consent. Datasets were de-identified prior to analysis.

2.6 Statistical analysis

Data were analyzed using IBM SPSS Statistics version 26. Continuous variables are summarized as mean ± SD and median [IQR]; categorical variables as n (%). One-way ANOVA compared age, height, weight, BMI, and A1AT across groups; where appropriate, Welch post-hoc tests estimated pairwise differences along with Hedges g and bootstrap 95% CIs. Distributional assumptions (Shapiro–Wilk; Levene) informed robustness checks and are reported in the Supplement.

Diagnostic performance was assessed using ROC curves, with AUC and bootstrap 95% CIs (resampling within groups). Youden's J defined operating thresholds; sensitivity, specificity, LR+, LR−, and PPV/NPV were reported at 10% and 30% TB prevalence to reflect typical Nigerian outpatient contexts. All tests were two-sided with $\alpha = 0.05$. Figures 1–2 depict (i) overlaid ROC curves with Youden points and (ii) A1AT distributions (violin + jitter) by group, with means and bootstrap 95% CIs, and the selected threshold.

3. Results

3.1 Participant characteristics

Baseline Age, sex, height, weight, and BMI did not differ significantly across groups (all omnibus $p > 0.10$). Sex distribution was comparable (χ^2 $p = 0.594$). (Table 1)

3.2 A1AT distributions by group

A1AT was substantially higher in NewDx TB (293.7 ± 73.9 mg/dL; median 311.7 [261.7–340.1]) versus Non-TB (151.5 ± 25.9; 150.7 [135.5–161.2]) and Treated TB (160.0 ± 22.6; 162.1 [145.7–170.8]); ANOVA $p < 0.001$(Table 1).

Welch post-hoc comparisons showed very large effects: NewDx vs Non-TB, $g = 2.53$ (95% CI 1.76–4.27; $p \approx 4.4 \times 10^{-10}$); NewDx vs Treated TB, $g = 2.41$ (95% CI 1.60–4.21; $p \approx 1.9 \times 10^{-9}$). Non-TB vs Treated TB was not significant ($p = 0.221$; $g = 0.35$). (Table 2; Figure 2)

3.3 Diagnostic performance

For Non-TB vs Newly Diagnosed TB, A1AT achieved AUC = 0.928 (bootstrap 95% CI 0.833–1.000) with an optimal Youden threshold ≈ 220 mg/dL, yielding sensitivity 0.88 and specificity 1.00. Predictive values at prevalence 10% were PPV = 1.00, NPV = 0.987; at 30%, PPV = 1.00, NPV = 0.951(Table 2; Figure 1).

For Non-TB vs All-TB (NewDx + Treated), AUC was 0.772 (95% CI 0.667–0.869) with threshold ≈ 167 mg/dL, sensitivity 0.68, specificity 0.80; PPV/NPV were 0.274/0.957 (10% prevalence) and 0.593/0.854 (30%). (Table 2; Figure 1)

Collectively, the data indicate excellent discrimination for ruling-in NewDx TB and moderate accuracy when treated cases are included—consistent with the therapeutic normalization of A1AT

Table 1: Participant characteristics and serum A1AT by group (N=25 per group)

Variable	Group	n	Mean ± SD	Median [IQR]	Min–Max	p-value (overall)
Age (years)	Non-TB	25	33.56 ± 11.44	31.00 [26.00, 40.00]	—	0.102 (ANOVA)
	Newly Diagnosed TB	25	36.20 ± 13.13	32.00 [28.00, 41.00]	—	
	Treated TB	25	41.84 ± 16.29	38.00 [30.00, 50.00]	—	
Sex	Non-TB	—	Male 7 (26.9%) / Female 18 (69.2%)	—	—	0.594 (χ^2)
	Newly Diagnosed TB	—	Male 10 (38.5%) / Female 15 (57.7%)	—	—	
	Treated TB	—	Male 10 (38.5%) / Female 15 (57.7%)	—	—	
Height (m)	Non-TB	25	1.67 ± 0.07	1.65 [1.63, 1.73]	—	0.792 (ANOVA)
	Newly Diagnosed TB	25	1.67 ± 0.07	1.65 [1.61, 1.73]	—	
	Treated TB	25	1.68 ± 0.07	1.68 [1.62, 1.73]	—	
Weight (kg)	Non-TB	25	71.80 ± 14.81	70.00 [63.00, 82.00]	—	0.286 (ANOVA)
	Newly Diagnosed TB	25	66.56 ± 13.01	68.00 [59.00, 73.00]	—	
	Treated TB	25	70.60 ± 7.40	72.00 [69.00, 75.00]	—	

Table 1 (cont): Participant characteristics and serum A1AT by group (N=25 per group)						
BMI (kg/m^2)	Non-TB	25	25.62 ± 4.61	25.97 [21.77, 29.04]	—	0.456 (ANOVA)
	Newly Diagnosed TB	25	24.13 ± 5.13	23.94 [22.10, 28.48]	—	
	Treated TB	25	25.06 ± 2.53	24.97 [23.45, 26.45]	—	
A1AT (mg/dL)	Non-TB	25	**151.50 ± 25.87**	150.70 [135.50, 161.21]	75.43–199.19	**<0.001 (ANOVA)**
	Newly Diagnosed TB	25	**293.66 ± 73.85**	311.70 [261.70, 340.10]	107.79–399.91	
	Treated TB	25	**160.04 ± 22.64**	162.10 [145.70, 170.80]	105.78–207.79	

Notes: To conserve space, Shapiro–Wilk and Levene results are moved to the Supplement; BMI is retained (height/weight shown for transparency). Means/medians are from observed data only.

Table 2: Discriminative performance and pairwise contrasts for A1AT (N=25)

Panel A: ROC metrics and decision thresholds

Contrast	AUC (95% CI, bootstrap)	Youden threshold (mg/dL)	Sens	Spec	LR+	LR−	PPV @10%	NPV @10%	PPV @30%	NPV @30%
Non-TB vs Newly Diagnosed TB	0.928 [0.833, 1.000]	220.20	0.880	1.000	—	0.12	1.000	0.987	1.000	0.951
Non-TB vs All-TB (NewDx + Treated)	0.772 [0.667, 0.869]	167.30	0.680	0.800	3.40	0.40	0.274	0.957	0.593	0.854

Table 2: Discriminative performance and pairwise contrasts for A1AT (N=25)

Panel B: Pairwise group comparisons (Welch t, Holm adjustment; effect size = Hedges g)

Comparison	Welch t	p-value	Hedges g [95% CI]	Holm-adjusted p
Non-TB vs Newly Diagnosed TB	−9.08	4.35×10^{-10}	−2.53 [−4.27, −1.76]	1.30×10^{-9}
Non-TB vs Treated TB	−1.24	0.221	−0.35 [−0.95, 0.19]	0.221
Newly Diagnosed TB vs Treated TB	8.65	1.86×10^{-9}	2.41 [1.60, 4.21]	3.72×10^{-9}

Notes: LR+ undefined when specificity = 1.00. PPV/NPV reported at 10% and 30% TB prevalence scenarios. All CIs from bootstrap on the observed samples.

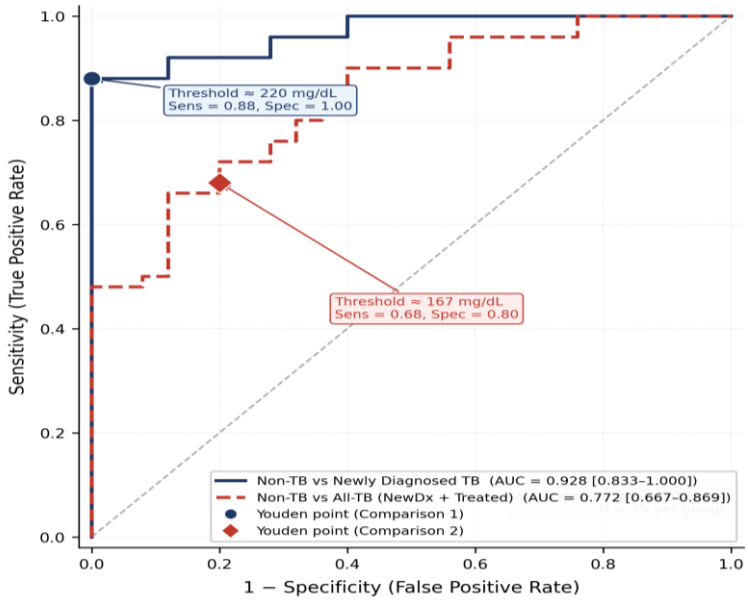

Figure 1: Overlaid ROC Curves (A1AT) annotated with AUCs and Youden points. (bootstrap 95% CI, N=25 per group)

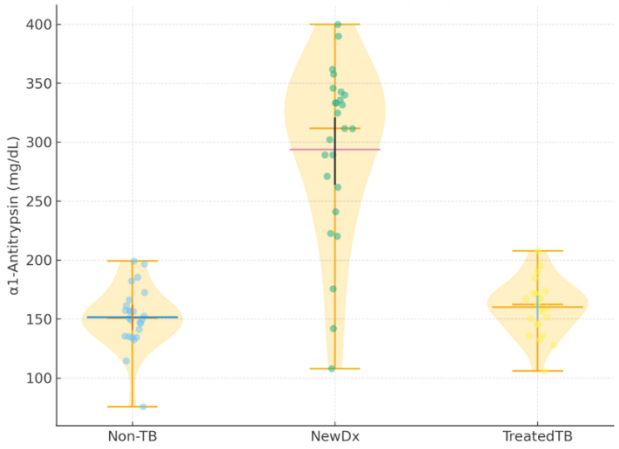

Figure 2: Group distributions of A1AT with means (bootstrap 95% CIs) and the Youden threshold line.

4. Discussion

This study demonstrates that serum α1-antitrypsin (A1AT) holds significant promise as a triage-stage biomarker within the Nigerian healthcare context. Its ability to distinguish new TB cases from non-TB individuals (AUC ~0.93) aligns with the acute-phase reactant behavior of A1AT, where levels are elevated at initial presentation. The subsequent convergence of A1AT values toward the non-TB range following successful treatment explains the reduced discriminative power when treated patients are included in the analysis (AUC ~0.77). This pattern is biologically coherent and programmatically relevant, as the primary need for triage occurs prior to treatment initiation.

Our findings are consistent with prior research. Proteomic studies, such as one in a Korean cohort, identified A1AT as a highly discriminative protein, with levels approximately 4.4-fold higher in TB patients than controls (Song et al., 2014). This corroborates the substantial effect size we observed. An earlier Nigerian study also documented elevated A1AT in pulmonary TB patients compared to controls, confirming its local biological relevance (Okpapi and Onyemelukwe, 1989). "This apparent contradiction is likely resolved by disease-stage heterogeneity, as A1AT depletion reported in severe TB is linked to neutrophil extracellular trap (NET) activity (de Melo et al., 2019)." Our cohort, representing ambulatory, newly diagnosed cases, reflects the stage where A1AT elevation is most pronounced.

From a programmatic perspective, A1AT addresses critical bottlenecks in Nigeria's TB case-finding efforts, which include challenges with sputum quality and limited cartridge capacity for molecular testing (Chukwu et al., 2024). "Because A1AT is measurable on standard biochemistry platforms already available in many district laboratories, it could efficiently pre-select patients for confirmatory testing." At a threshold near 220 mg/dL, our data showed high sensitivity with perfect specificity for new diagnoses, a performance profile that compares favorably with C-reactive protein (CRP). While CRP is WHO-endorsed and operationally simple, it often fails to achieve the target product profile's specificity requirements in general adult populations, frequently falling short of the desired high sensitivity with moderate specificity outside specific sub-groups (Calderwood et al., 2023; Derendinger et al., 2024). Although a direct comparison was not performed here, A1AT may offer improved specificity in this setting, which could reduce unnecessary confirmatory testing and diagnostic delays.

This study is not free of limitations. Its case-control design and modest sample size limit the precision of our estimates, necessitating future validation in larger, multicenter cohorts with HIV-stratified analyses. We did not perform *SERPINA1* genotyping to identify alpha-1-antitrypsin deficiency (AATD); however, this inherited condition is rare and results in lower A1AT levels, thereby biasing our results conservatively against the observed elevations (Meseeha and Attia, 2024). Finally, cross-platform harmonization of A1AT assays will be crucial for scaled deployment.

Despite these limitations, our conclusions are twofold. First, A1AT is a highly promising triage biomarker for Nigerian outpatient settings, particularly where diagnostic capacity is constrained. Second, its kinetic profile suggests potential utility as a treatment-response marker, warranting longitudinal investigation. In the near term, incorporating A1AT into a small, low-complexity host-response panel could enhance diagnostic accuracy while remaining feasible for peripheral implementation in Nigeria.

5. Conclusion

In routine Nigerian care, serum α1-antitrypsin discriminates newly diagnosed pulmonary TB from non-TB with excellent accuracy and a practical cut-point (~220 mg/dL) suitable for triage. Discrimination decreases to moderate when treated cases are pooled into the TB-positive class, reflecting biologic normalization and having less relevance for the triage decision. These data support prospective, multi-site validation and operational pilots embedding A1AT-guided referral to confirmatory testing within Nigeria's TB diagnostic cascade.

Recommendations

- Pilot A1AT-guided triage in peripheral clinics, calibrating the ~220 mg/dL threshold locally and embedding internal QC/external proficiency.
- Compare head-to-head with CRP and evaluate two–four marker panels that include A1AT to optimize sensitivity/specificity trade-offs.

Test implementation impact (time-to-diagnosis, cartridge utilization, costs) and stratify results by HIV status and common co-morbid inflammatory conditions.

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