**Table C-1. Studies of serology accuracy**

| Author, Year | Number of Participants,Populations | Type of Diagnostic Test,Cut-Off Value | OutcomesSensitivity,Specificity,Positive Predictive Value,Negative Predictive Value | QUADAS |
| --- | --- | --- | --- | --- |
| Barada et al., 2014[31](#_ENREF_31) | Number of Participants: 999 AdultsComments: Marsh 2 & 3 were considered celiac. In addition, authors classified 1 person with Marsh 1 and positive EMA as celiac. | Type of Diagnostic Test: EMA IgACut-off value: NRType of Diagnostic Test: tTG IgACut-off value: NRType of Diagnostic Test: Combined screen tTG IgA, DGP IgACut-off value: NR | Sensitivity: 72.2%Specificity: 99.7%Positive predictive value: 90Negative predictive value: 99.2Sensitivity: 72.2%Specificity: 98.4%Positive predictive value: 44.8Negative predictive value: 99.5Sensitivity: 72.2%Specificity: 97.4%Positive predictive value: 34.2Negative predictive value: 99.5 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Basso et al., 2011[32](#_ENREF_32) | Number of Participants: 703 Adults | Type of Diagnostic Test: tTG IgACut-off value: 100 U/mLType of Diagnostic Test: tTG IgACut-off value: 17.5 U/mLType of Diagnostic Test: tTG IgACut-off value: 20 UType of Diagnostic Test: tTG IgACut-off value: 24 U/mLType of Diagnostic Test: tTG IgACut-off value: 75.6 U/mLType of Diagnostic Test: tTG IgACut-off value: 909.3 U/mL | Sensitivity: 75.7%Specificity: 100%Positive predictive value: 100Negative predictive value: 82.4Sensitivity: 94.5%Specificity: 97.1%Positive predictive value: 96.6Negative predictive value: 95.3Sensitivity: 94.2%Specificity: 97.3%Positive predictive value: 96.9Negative predictive value: 95Sensitivity: 96.3%Specificity: 81.3%Positive predictive value: 81.9Negative predictive value: 96.2Sensitivity: 90.9%Specificity: 96.5%Positive predictive value: 95.8Negative predictive value: 92.3Sensitivity: 62.6%Specificity: 100%Positive predictive value: 100Negative predictive value: 75.2 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: NoCould patient flow have introduced bias: Not Applicable |
| Basso et al., 2011[32](#_ENREF_32) | Number of Participants: 703 Adults | Type of Diagnostic Test: tTG IgA, DGP IgACut-off value: 145 UType of Diagnostic Test: tTG IgA, DGP IgACut-off value: 20 UType of Diagnostic Test: tTG IgA, DGP IgACut-off value: 32 UType of Diagnostic Test: tTG IgGCut-off value: 20 U/mLType of Diagnostic Test: tTG IgGCut-off value: 47.6 U/mLType of Diagnostic Test: tTG IgGCut-off value: 976.8 U/mL | Sensitivity: 65.3%Specificity: 100%Positive predictive value: 100Negative predictive value: 76.6Sensitivity: 96.7%Specificity: 89.8%Positive predictive value: 89.3Negative predictive value: 96.8Sensitivity: 95.4%Specificity: 95.7%Positive predictive value: 95.2Negative predictive value: 96Sensitivity: 96.7%Specificity: 83.4%Positive predictive value: 83.7Negative predictive value: 96.6Sensitivity: 93.3%Specificity: 94.1%Positive predictive value: 93.3Negative predictive value: 94.1Sensitivity: 59.6%Specificity: 100%Positive predictive value: 100Negative predictive value: 73.8 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: NoCould patient flow have introduced bias: Not Applicable |
| Bienvenu et al., 2014[33](#_ENREF_33) | Number of Participants: 45Population: Selective IgA deficient children  | Type of Diagnostic Test: CD-LFIA (detects both human IgA and IgG anti-DGP)Cut-off value: NA | Sensitivity: 100.0%Specificity: 89.2%Negative predictive value: 100.0% | QUADAS Domain 1Consecutive or random sample: YesCase control design: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: UnclearAll patients received same test: Unclear All patients included analysis: YesCould patient flow have introduced bias: High |
| Cekin et al., 2012[34](#_ENREF_34) | Number of Participants: 84 Adults with Iron Deficiency | Type of Diagnostic Test: EMA IgAType of Diagnostic Test: EMA IgG | Sensitivity: 100%Specificity: 98.72%Positive predictive value: 85.71Negative predictive value: 100Sensitivity: 33.33%Specificity: 96.15%Positive predictive value: 40Negative predictive value: 94.94 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Dahlbom et al., 2010[35](#_ENREF_35) | Number of Participants: 301 Children and Adults | Type of Diagnostic Test: tTG IgACut-off value: >3 U m/LType of Diagnostic Test: tTG IgGCut-off value: >3 U m/L | Sensitivity: 100%Specificity: 99.24%Positive predictive value: 99.42Negative predictive value: 100Sensitivity: 84.12%Specificity: 98.47%Positive predictive value: 98.62Negative predictive value: 82.69 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: Not ApplicableBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Dahle et al., 2010[36](#_ENREF_36) | Number of Participants: 176 Adults | Type of Diagnostic Test: EMA IgACut-off value: Serum dilution 1/5Type of Diagnostic Test: tTG IgACut-off value: 5 U/mLType of Diagnostic Test:, DGP IgA or DGP IgGCut-off value: 20 Au/mLType of Diagnostic Test: tTG IgG or IgA combined with DGP IgG or IgACut-off value: 20 Au/mLType of Diagnostic Test: tTG IgG or IgA combined with DGP IgG or IgACut-off value: 35 AU/mL | Sensitivity: 61%Specificity: 100%Sensitivity: 76%Specificity: 95%Sensitivity: 87%Specificity: 96%Sensitivity: 91%Specificity: 80%Sensitivity: 85%Specificity: 98% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: NoAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| DeGaetani et al., 2013[37](#_ENREF_37) | Number of Participants: 59 Adults with prior negative serology but villious atrophy. HLA test was used to rule out celiac disease. | Type of Diagnostic Test: HLA DQ2, HLA DQ2 | Sensitivity: 100%Specificity: 18.18%Positive predictive value: 29.41Negative predictive value: 100 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: UnclearBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Dutta et al., 2010[38](#_ENREF_38) | Number of Participants: 92 symptomatic adults in IndiaComment: Unclear why tTG IgG test was used  | Type of Diagnostic Test: tTG IgGCut-off value: >15 U/mL | Sensitivity: 77.8%Specificity: 89.1%Positive predictive value: 63.6Negative predictive value: 94.2 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Emami et al., 2012[39](#_ENREF_39) | Number of Participants: 130Population: IgA Deficient adults in Iran | Type of Diagnostic Test: tTG IgACut-off value: >10 AU/ml | Sensitivity: 38.46%Specificity: 96.58%Positive predictive value: 55.56Negative predictive value: 93.39 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Harrison et al., 2013[40](#_ENREF_40) | Number of Participants: 12,289, age unclear. Some IgA deficient, but number not reported | Type of Diagnostic Test: tTG IgA, Cut-off value: 5 U/mLType of Diagnostic Test: tTG IgA, tTG IgGCut-off value: 5 U/mL | Sensitivity: 86.8%Specificity: 99.9%Sensitivity: 92.1%Specificity: 99.9% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Kaukinen et al., 1999[41](#_ENREF_41) | Number of Participants: 26Population: Patients with endocrinologic disorders in Finland | Type of Diagnostic Test: HLA DQ2, HLA DQ2 | Sensitivity: 100%Specificity: 33.33%Positive predictive value: 5.26Negative predictive value: 100 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: NoAll patients received same test: NoAll patients included analysis: NoCould patient flow have introduced bias: High |
| Mansour et al., 2011[42](#_ENREF_42) | Number of Participants: 62Population: Type 1 diabetes, Iraq | Type of Diagnostic Test: EMA IgACut-off value: 20 U/mLType of Diagnostic Test: tTG IgACut-off value: 15 U/mLType of Diagnostic Test: tTG IgGCut-off value: 15 U/mL | Sensitivity: 71.43%Specificity: 96.36%Positive predictive value: 71.43Negative predictive value: 96.36Sensitivity: 71.43%Specificity: 92.73%Positive predictive value: 55.56Negative predictive value: 96.23Sensitivity: 57.14%Specificity: 92.73%Positive predictive value: 50Negative predictive value: 94.44 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Mozo et al., 2012[43](#_ENREF_43) | Number of Participants: 200 | Type of Diagnostic Test: DGP IgACut-off value: >7 U/mLType of Diagnostic Test: DGP IgGCut-off value: >7 U/mLType of Diagnostic Test: tTG IgACut-off value: >7 U/mL | Sensitivity: 96%Specificity: 96%Positive predictive value: 96Negative predictive value: 96Sensitivity: 95%Specificity: 99%Positive predictive value: 98.9Negative predictive value: 95.2Sensitivity: 89%Specificity: 94%Positive predictive value: 93.7Negative predictive value: 89.5 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: NoAll patients received same test: Not ApplicableAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Nevoral et al., 2013[44](#_ENREF_44) | Number of Participants: 345 children and adolescentsNumber of Participants: 32 first degree relativesNumber of Participants: 263 with Marsh 2 or 3 classificationNumber of Participants: 40 Type 1 diabetes | Type of Diagnostic Test: tTG IgA, EMA IgGCut-off value: 12 U/mLType of Diagnostic Test: tTG IgA, EMA IgACut-off value: 12 U/mLType of Diagnostic Test: tTG IgA, EMA IgACut-off value: 12 U/mLType of Diagnostic Test: tTG IgA, EMA IgACut-off value: 12 U/mLComment: New ESPGHAN algorithm used | Sensitivity: 76%Specificity: 85%Positive predictive value: 94Negative predictive value: 53Sensitivity: 81%Specificity: 70%Sensitivity: 83%Specificity: 67%Sensitivity: 93%Specificity: 64% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Olen et al., 2012[45](#_ENREF_45) | Number of Participants: 69Population: <2 years oldNumber of Participants: 408Population: all patientsNumber of Participants: 67Population: <2 years oldNumber of Participants: 530Population: all patientsComments: 93 individuals were excluded from study because the serology analyses had not been carried out at the participating immunology departments. Also, it isn’t clear why some patients did not undergo DGP tests. | Type of Diagnostic Test: DGP IgACut-off value: NRType of Diagnostic Test: DGP IgACut-off value: NRType of Diagnostic Test: tTG IgACut-off value: NRType of Diagnostic Test: tTG IgACut-off value:NR | Sensitivity: 100%Specificity: 31%Positive predictive value: 44Sensitivity: 91%Specificity: 26%Positive predictive value: 51Sensitivity: 96%Specificity: 98%Positive predictive value: 96Sensitivity: 94%Specificity: 86%Positive predictive value: 88 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Sakly et al., 2012[46](#_ENREF_46) | Number of Participants: 297 adults and children | Type of Diagnostic Test: DGP IgACut-off value: 25 IU/mLType of Diagnostic Test: DGP IgGCut-off value: 25 IU/mL | Sensitivity: 97%Specificity: 90.7%Sensitivity: 94.2%Specificity: 95.4% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Srinivas et al., 2014[47](#_ENREF_47) | Number of Participants: 752 Population: Clinical features of celiac disease | Type of Diagnostic Test: tTG IgACut-off value: : <10 IU/mLType of Diagnostic Test: IgA EMA | Sensitivity: 0.83Specificity: 0.96Sensitivity: 0.80Specificity: 0.99Positive predictive value: Negative predictive value:  | QUADAS Domain 1Consecutive or random sample: YesCase control design: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: NoAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: High |
| Srinivas et al., 2013[48](#_ENREF_48) | Number of Participants: 75Number of Participants: 102Number of Participants: 71 | Type of Diagnostic Test: EMA IgGType of Diagnostic Test: tTG IgACut-off value: 10 IU/mLType of Diagnostic Test: tTG IgA, EMA IgA | Sensitivity: 83%Specificity: 99%Positive predictive value: 93Negative predictive value: 98Sensitivity: 84%Specificity: 96%Positive predictive value: 72Negative predictive value: 98Sensitivity: 83%Specificity: 99%Positive predictive value: 97Negative predictive value: 98 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Sugai et al., 2010[49](#_ENREF_49) | Number of Participants: 17 IgA tTG negative adults with villous atrophyComments: Original N = 22, five patients refused biopsy. | Type of Diagnostic Test: DGPType of Diagnostic Test: tTG IgA, DGP IgA | Sensitivity: 35.71%Specificity: 100%Sensitivity: 42.86%Specificity: 100% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: NoAll patients received same test: YesAll patients included analysis: NoCould patient flow have introduced bias: High |
| Swallow et al., 2013[50](#_ENREF_50) | Number of Participants: 733 AdultsResults when Marsh 1-2 considered celiacNumber of Participants: 756 AdultsResults when Marsh 1-3 considered celiacNumber of Participants: 756 AdultsResults when Marsh 3 considered celiacNumber of Participants: 733Adults Results when Marsh 1-2 considered celiacNumber of Participants: 756 Adults Results when Marsh 1-3 considered celiacNumber of Participants: 756Population: Marsh 3Comments: 473 patients were excluded because only one of the two serology tests was performed. 14 of these were diagnosed as CD via biopsy. | Type of Diagnostic Test: EMA IgAType of Diagnostic Test: EMA IgAType of Diagnostic Test: EMA IgAType of Diagnostic Test: , tTG IgAfollowed by EMA IgA, (NICE two step strategy) Type of Diagnostic Test: , tTG IgAfollowed by EMA IgA, (NICE two step strategy)Type of Diagnostic Test: , tTG IgAfollowed by EMA IgA, (NICE two step strategy) | Sensitivity: 42.9%Specificity: 99.5%Positive predictive value: 42.9Negative predictive value: 99.5Sensitivity: 73.3%Specificity: 99.5%Positive predictive value: 84.6Negative predictive value: 98.9Sensitivity: 82.6%Specificity: 99.1%Positive predictive value: 73.1Negative predictive value: 99.5Sensitivity: 57.1%Specificity: 97.3%Positive predictive value: 16.7Negative predictive value: 99.6Sensitivity: 80%Specificity: 97.3%Positive predictive value: 54.6Negative predictive value: 99.2Sensitivity: 87%Specificity: 96.9%Positive predictive value: 46.5Negative predictive value: 99.6 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Swallow et al., 2013[50](#_ENREF_50) | Number of Participants: 733AdultsResults when Marsh 1-2 considered celiacNumber of Participants: 756 AdultsResults when Marsh 1-3 considered celiacNumber of Participants: 756 AdultsResults when Marsh 3 considered celiacas CD via biopsy. | Type of Diagnostic Test: tTG IgAType of Diagnostic Test: tTG IgAType of Diagnostic Test: tTG IgA | Sensitivity: 42.9%Specificity: 99.5%Positive predictive value: 42.9Negative predictive value: 99.5Sensitivity: 73.3%Specificity: 99.5%Positive predictive value: 84.6Negative predictive value: 98.9Sensitivity: 82.6%Specificity: 99.1%Positive predictive value: 73.1Negative predictive value: 99.5 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Van Meensel et al., 2004[51](#_ENREF_51) | Number of Participants: 175 AdultsComment: 5 patients were IgA deficient | Type of Diagnostic Test: tTG IgACut-off value: 10 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 15 kilounitsType of Diagnostic Test: tTG IgACut-off value: 19.05 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 2.64 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 20 kilounitsType of Diagnostic Test: tTG IgACut-off value: 20 kilounits/L | Sensitivity: 94%Specificity: 100%Sensitivity: 94%Specificity: 100%Sensitivity: 93%Specificity: 100%Sensitivity: 96%Specificity: 99%Sensitivity: 97%Specificity: 96%Sensitivity: 93%Specificity: 100% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Van Meensel et al., 2004[51](#_ENREF_51) | Number of Participants: 175 AdultsComment: 5 patients were IgA deficient | Type of Diagnostic Test: tTG IgACut-off value: 20.47 kilounitsType of Diagnostic Test: tTG IgACut-off value: 3.13 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 3.69 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 4 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 4.43 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 40 kilounits/L | Sensitivity: 97%Specificity: 100%Sensitivity: 96%Specificity: 99%Sensitivity: 96%Specificity: 100%Sensitivity: 93%Specificity: 99%Sensitivity: 99%Specificity: 99%Sensitivity: 96%Specificity: 96% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Van Meensel et al., 2004[51](#_ENREF_51) | Number of Participants: 175 AdultsComment: 5 patients were IgA deficient | Type of Diagnostic Test: tTG IgACut-off value: 5 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 50 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 56.9 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 7 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 7 kilounits/LType of Diagnostic Test: tTG IgACut-off value: 7.16 kilounits/L | Sensitivity: 93%Specificity: 99%Sensitivity: 93%Specificity: 93%Sensitivity: 91%Specificity: 99%Sensitivity: 91%Specificity: 100%Sensitivity: 97%Specificity: 100%Sensitivity: 97%Specificity: 100% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Van Meensel et al., 2004[51](#_ENREF_51) | Number of Participants: 175Comment: 5 patients were IgA deficient | Type of Diagnostic Test: tTG IgACut-off value: 7.98 kilounitsType of Diagnostic Test: tTG IgACut-off value: 9.73 kilounits/L | Sensitivity: 96%Specificity: 100%Sensitivity: 94%Specificity: 100% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Vermeersch et al., 2010[52](#_ENREF_52) | Number of Participants: 827 (599 adults, 228 children)Number of Participants: 827Number of Participants: 827Number of Participants: 827Number of Participants: 827Number of Participants: 827 | Type of Diagnostic Test: DGP IgACut-off value: >7Type of Diagnostic Test: DGP IgGCut-off value: 10Type of Diagnostic Test: DGP IgGCut-off value: 20Type of Diagnostic Test: DGP IgGCut-off value: 25Type of Diagnostic Test: DGP IgGCut-off value: >7Type of Diagnostic Test: tTG IgACut-off value: 7 | Sensitivity: 65.1%Specificity: 99.1%Sensitivity: 79.1%Specificity: 97.6%Sensitivity: 83.7%Specificity: 99.3%Sensitivity: 76.7%Specificity: 99.2%Sensitivity: 86%Specificity: 97.3%Sensitivity: 84.9%Specificity: 92% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Vermeersch et al., 2010[52](#_ENREF_52) | Number of Participants: 827Number of Participants: 827Number of Participants: 827Number of Participants: 827 | Type of Diagnostic Test: tTG IgACut-off value: >15Type of Diagnostic Test: tTG IgACut-off value: >7Type of Diagnostic Test: tTG IgGCut-off value: >15Type of Diagnostic Test: tTG IgGCut-off value: >7 | Sensitivity: 88.4%Specificity: 94.9%Sensitivity: 83.7%Specificity: 98.4%Sensitivity: 60.5%Specificity: 98.1%Sensitivity: 38.4%Specificity: 98.5% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Vermeersch et al., 2010[53](#_ENREF_53) | Number of Participants: 588 AdultsNumber of Participants: 588 Adults | Type of Diagnostic Test: tTG IgACut-off value: >15 U/mLType of Diagnostic Test: tTG IgACut-off value: >=7 U/mL | Sensitivity: 86%Specificity: 95%Sensitivity: 95.3%Specificity: 92.7%Positive predictive value: 50.6 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Vermeersch et al., 2012[54](#_ENREF_54) | Number of Participants: 649 Adults and ChildrenComments: Retrospective study; the controls spanned years 2004 to 2006, while cases spanned years 2001 to 2009. | Type of Diagnostic Test: DGP IgA + tTG IgG\*Cut-off value: 20 U/mLType of Diagnostic Test: DGP IgA + tTG IgG\*Cut-off value: 7 U/mLType of Diagnostic Test: DGP IgGCut-off value: 20 U/mLType of Diagnostic Test: DGP IgGCut-off value: 7 U/mLType of Diagnostic Test: tTG IgACut-off value: 20 U/mLType of Diagnostic Test: tTG IgACut-off value: 7 U/mL\*Combined test determines whether patient has low IgA and will need IgG tests instead of IgA tests | Sensitivity: 89.7%Specificity: 93.3%Sensitivity: 88.8%Specificity: 95.6%Sensitivity: 85%Specificity: 99.3%Sensitivity: 86.9%Specificity: 96.7%Sensitivity: 84.1%Specificity: 95.9%Sensitivity: 81.3%Specificity: 98.5% | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: UnclearAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Unclear |
| Wakim-Fleming et al., 2014[55](#_ENREF_55) | Number of Participants: 204Population: Consecutive patients with biopsy proven cirrhosis | Type of Diagnostic Test: EMASerum dilution >= 1/10Type of Diagnostic Test: TTGCut-off value: above 20 U | Sensitivity: 1.00Specificity: 1.00Positive predictive value: Negative predictive value:Sensitivity: 1.00Specificity: 0.96Positive predictive value: Negative predictive value: | QUADAS Domain 1Consecutive or random sample: YesCase control design: YesInappropriate exclusions: YesBiased patient Selection: LowQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Low |
| Wolf et al., 2014[57](#_ENREF_57) | Number of Participants: 1071 childrenPopulation: Selective IgA deficiency (sIgAD) was found in 27 patients | Type of Diagnostic Test: tTG IgACut-off value: >10 U/mLType of Diagnostic Test: DGP IgGCut-off value: >10 U/mL | Sensitivity: 0.88Specificity: 0.97 Sensitivity: 0.89Specificity: 0.95 when added to tTG in children without IgA deficiencySensitivity: 0.29Specificity: 1.00when added to tTG in children WITH IgA deficiency  | QUADAS Domain 1Consecutive or random sample: YesCase control design: NoInappropriate exclusions: YesBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: YesPrespecified test threshold: YesBias due to testing: LowQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: YesBias due to reference test: LowQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Low |
| Zanini et al., 2012[58](#_ENREF_58) | Number of Participants: 263 Adults, (Brand B used)Number of Participants: 393 Adults, (Brand A used)Number of Participants: 289Adults, (Brand C used)Number of Participants: 393Number of Participants: 289Number of Participants: 263 | Type of Diagnostic Test: tTG IgACut-off value: 16 U/mLType of Diagnostic Test: tTG IgACut-off value: 21 U/mLType of Diagnostic Test: tTG IgACut-off value: 24 U/mLType of Diagnostic Test: tTG IgACut-off value: 35 U/mLType of Diagnostic Test: tTG IgACut-off value: 40 U/mLType of Diagnostic Test: tTG IgACut-off value: 48 U/mL | Sensitivity: 89.4%Specificity: 88.1%Positive predictive value: 90.3Negative predictive value: 77.4Sensitivity: 38.2%Specificity: 97.4%Positive predictive value: 95.8Negative predictive value: 50.7Sensitivity: 58.8%Specificity: 99%Positive predictive value: 99Negative predictive value: 60.7Sensitivity: 10.1%Specificity: 100%Positive predictive value: 100Negative predictive value: 42Sensitivity: 43.1%Specificity: 100%Positive predictive value: 100Negative predictive value: 53.1Sensitivity: 69.7%Specificity: 58.8%Positive predictive value: 100Negative predictive value: 60.3 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |
| Zanini et al., 2012[58](#_ENREF_58) | Number of Participants: 393Number of Participants: 289Number of Participants: 263 | Type of Diagnostic Test: tTG IgACut-off value: 7 U/mLType of Diagnostic Test: tTG IgACut-off value: 8 U/mLType of Diagnostic Test: tTG IgACut-off value: 80 U/mL | Sensitivity: 94.5%Specificity: 76.1%Positive predictive value: 85.9Negative predictive value: 90.1Sensitivity: 88.1%Specificity: 92.2%Positive predictive value: 94.6Negative predictive value: 83.3Sensitivity: 59.1%Specificity: 43.1%Positive predictive value: 100Negative predictive value: 52.9 | QUADAS Domain 1Consecutive or random sample: YesCase control design avoided: YesInappropriate exclusions: NoBiased patient Selection: HighQUADAS Domain 2Blinded interpretation of index test results: UnclearPrespecified test threshold: YesBias due to testing: UnclearQUADAS Domain 3Valid reference standard: YesBlinded analysis of reference test: UnclearBias due to reference test: UnclearQUADAS Domain 4Appropriate interval between reference and index test: YesAll patients received reference test: YesAll patients received same test: YesAll patients included analysis: YesCould patient flow have introduced bias: Not Applicable |

Table Notes: Au/ml – Absorbance Units per Milliliter; DGP – Deamidated Gliadin Peptide (DGP); DM = Diabetes; EMA – Endomysial Antibodies; HLA Human Leukocyte Antigen; IgA - Immunoglobulin A; IgG - Immunoglobulin G; L – Liter; NR – Not Reported; QUADAS – Quality Assessment of Diagnostic Studies; tTG - Anti-tissue Transglutaminase; U – Units; U/mL – Units per milliliter