Detection timing and process

GERD attack	Collect samples and complete detection within 15min after GERD attacks.
Suspected nocturnal GERD	Patients, standing upright, may collect samples and complete detection before eating breakfast or brushing teeth after they wake up in the morning.
Persistent symptoms	Within 1–2 hours after meals, or as directed by a physician.
Outpatient service	Pepsin levels after patients wake up and have lunch are recommended for detection (the time point after lunch is preferred).

① Expel saliva directly into the test tube until reaching the 1-mL mark

② Securely cap the reagent tube and shake well

③ Centrifuge the sample at 4000 rpm for 5 minutes

④ Take 80μl of test solution from the upper clear liquid, add it to 240μl of transfer buffer, and mix well

⑤ Finally, extract the mixed solution and drip it into the sample well, wait for 5-15 minutes to get the result

References:

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease[J]. Am J Gastro-enterol, 2013, 108 (3):308-328.

2. Zhiwei Hu, Jimin Wu, Zhonghao Wang. Diagnostic Summary of Gastroesophagus Airway Reflux Disease [J]. Chinese Medical Digest (Otorhinolaryn-gology), 2018, 33 (1): 47-52

3. Parsel SM, Wu EL, Riley CA, et al. Gastroesophageal and Lary ng opharyngeal Reflux Associated With Laryngeal Malignancy: A Systematic Review and Meta-analysis[J]. Clin Gastroenterol Hepatol, 2019, 17(7):1253-1264.

YouBest (Zhejiang) Biotechnology Co., Ltd.

Address: Zhenxing East Road, Building 5, Unit 501,Donghu Sub-district, Linping District, Hangzhou City, Zhejiang Province
Email: sales@youbest.co **Web:** www.youbest.co

Please see the instruction for contraindications or cautions

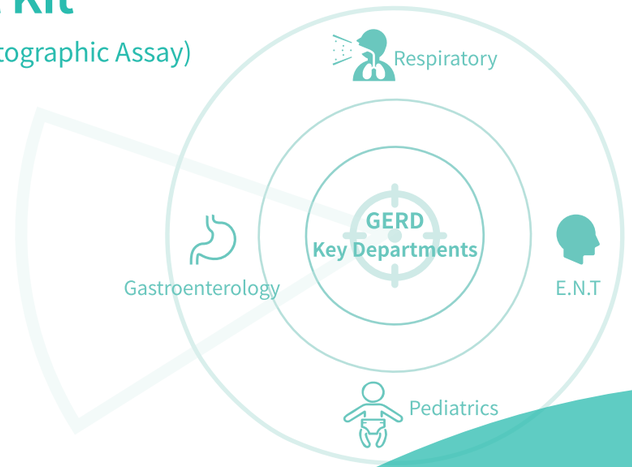
YOUBEST™ 优博思™

A New Method of Diagnosis/Rule-out of Gastroesophageal Reflux Disease (GERD)

Providing objective grounds for GERD diagnosis

Pepsin Rapid Test Kit

(Colloidal Gold Immunochromatographic Assay)



Fast Accurate Non-invasive

YouBest (Zhejiang) Biotechnology Co., Ltd.

About GERD

Definition of GERD: GERD refers to a disease of a series of symptoms, end-organ effects and/or complications caused by the back-flow of stomach contents into the esophagus, the oral cavity (including the throat) and/or the lungs. Extraesophageal Reflux (EER) is an important part of GERD.

High incidence rate

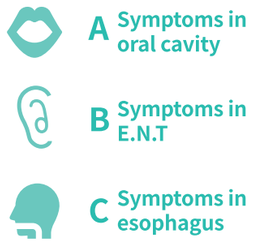
The incidence rate of GERD is 10%-20%. In China, there are about 200 million GERD patients, most of whom have not been confirmed with the disease or accepting effective treatments.

Symptoms are various but not typical, leading to a low diagnostic rate and yet a high misdiagnosis rate

Missed diagnosis or misdiagnosis often occurs in patients with GERD-caused symptoms like “cough, asthma, pharyngitis and otitis media”.

Extraesophageal Symptoms

Location	Diseases
Ears	Secretory otitis media, eustachian tube dysfunction.
Nose	Non-allergic rhinitis, chronic rhinitis – sinusitis (multisinus), nasal polyp.
Pharynx	Chronic pharyngitis, adenoidal hypertrophy, pharyngeal paraesthesia, tonsil hypertrophy.
Oral Cavity	Recurrent oral ulcer, dental caries, etc.
Throat	Chronic laryngitis, vocal cord oedema, vocal cord hypertrophy, contact ulcer and granuloma, laryngospasm, laryngeal cancer (without history of smoking), abnormal vocal cord movements, neoplasm in vocal cord, leukoplakia of the vocal cord, subglottic stenosis, hoarseness.
Lower Airways	Chronic cough, asthma (non-allergic), chronic bronchitis, interstitial pneumonia, pulmonary fibrosis, chronic obstructive pulmonary disease (COPD), nocturnal paroxysmal dyspnea, bronchiectasis, cystic fibrosis, rejection post lung transplant.



Significant risks

- Long course of disease with high recurrence rate
- Great probability of missed diagnosis and misdiagnosis leads to progression of disease, extra costs for treatment and adverse drug reactions
- Likely to develop more serious diseases
- May develop depression that can seriously affect the life quality of the patient

Limitations of common diagnosis methods

- Detection of pepsin in body fluid
- Upper gastrointestinal contrast
- 24h/PH-impedance monitoring
- High-resolution esophageal manometry
- DX-PH monitoring
- Electronic gastroscopy

Test	Sensitivity	Specificity	Influence factors and exceptions
PPI test	68-78%	44-54%	Doses, medication compliance, PPI resistance, refractory GERD
Endoscope	30%		Non-erosive reflux disease (NERD)
pH monitoring	66%		Non-acidic/weakly-acidic reflux
Questionnaire	63%	67%	Reflux sensitivity/Subjective or unclear description of symptoms by patients/ Extraesophageal Symptoms

Pepsin Rapid Test Kit

—— Quickly capture pepsin and provide the test result in 15 min

—— Only gastric chief cells secrete pepsin, so pepsin detected in saliva/sputum indicates the reflux

Consensus on Multi-disciplinary Diagnosis and Treatment of GERD in China

Monitoring pepsin in saliva, nasal secretion, sputum and other secretions is a handy and non-invasive diagnosis method and is expected to be widely applied to diagnosis of LPRD. [Expert opinion: A+ (58.3%), A (16.7%), A- (16.7%), Uncertain (8.3%)]

Pepsin detected in extraesophageal organs or tissues serves as a direct evidence or clue for analyzing the correlation between GERD and pulmonary diseases, E.N.T. diseases.

Pepsin may be detected in esophagus, pharynx, throat, airways, oral cavity, nasal cavity, eustachian tube, auris media, lacrimal gland and other body parts of GERD patients, which supports the diagnosis of GERD.

Diagnosis and Treatment Guidelines for Cough (2021 Edition)

Salivary pepsin testing can be used for GERD diagnosis and has been included in the latest Diagnosis and Treatment Guidelines for Cough.

Diagnosis and Treatment Guidelines for Chronic Obstructive Pulmonary Disease (COPD) (2021 Edition)

Gastroesophageal reflux disease (GRED) is an independent risk factor for an acute exacerbation of COPD.

Clinical Application

Field	Symptoms
Gastroenterology	Patients with typical heartburn, reflux, heartburn (secretion of too much saliva) and nausea, belching, slow digestion, early satiety, upper abdominal pain, abdominal distension, vomiting, hematemesis, chest pain (precordial part) and other digestive reflux symptoms.
Respiratory	GERD should be ruled out or determined before specialized treatment is provided for chronic cough, throat clearing, short breath, sleep apnea, snoring, asthma attack (wheezing), exacerbated COPD, chronic nasal sinusitis and other respiratory symptoms.
E. N. T.	GERD should be ruled out or determined before specialized treatment is provided for hoarseness, pharyngeal pain (abnormal sensation of pharynx), dysphagia, globus hystericus, pharyngitis, dental caries, speech disorder and other ENT symptoms.
Pediatrics	Pediatric patients with symptoms listed above As it is more difficult for pediatric patients to give accurate description, more caution is required for giving them invasive examination, while the routine examination has limitations.

Significance of screening/confirming GERD through detection of pepsin:

- Due to exceptional cases and limitations of traditional tests, a large amount of GERD patients have not been diagnosed in a single-item examination, while detection of pepsin can provide objective grounds for GERD diagnosis
- Missed diagnosis or misdiagnosis often occurs in patients with “cough, asthma, pharyngitis and otitis media” caused by GERD. These patients are often given routine treatments without anti-reflux treatment, so the root cause cannot be solved. As a result, the effect of treatment is poor and patients experience recurrence of the disease and non-remitting symptoms
- Detection of pepsin presents notable value in identifying and diagnosing GERD.
- For patients with negative endoscopic findings and PPI-refractory patients, pepsin detection can further identify NERD and non-acidic/weakly-acidic reflux

  Pepsin detection can be used for assessing the effect of PPI test, patient prognosis

Significance of ruling out GERD through detection of pepsin

- It can reduce unnecessary anti-reflux treatments as well as patient’s adverse reaction to PPI test.
- It can reduce further invasive examination to release the burdens on patients.